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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0867; Airspace Docket No. 21–AAL–39]

RIN 2120–AA66

Establishment of United States Area Navigation (RNAV) Route T–435; Sand Point, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes United States Area Navigation (RNAV) route T–435 in the vicinity of Sand Point, AK in support of a large and comprehensive T–route modernization project for the state of Alaska.

DATES: Effective date 0901 UTC, September 8, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, 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 Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jesse Acevedo, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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 the 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 expands the availability of RNAV routing in Alaska and improve the efficient flow of air traffic within the National Airspace System by lessening the dependency on ground based navigation.

History

The FAA published a notice of proposed rulemaking for Docket No. FAA–2021–0867 in the **Federal Register** (86 FR 59065; October 26, 2021), establishing United States Area Navigation (RNAV) route T–435 in the vicinity of Sand Point, AK in support of a large and comprehensive T-route modernization project for the state of Alaska. Interested parties were invited to participate in this rulemaking effort by submitting comments on the proposal. There were no comments received.

United States Area Navigation Routes are published in paragraph 6011 of FAA Order JO 7400.11F dated August 10, 2021 and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The RNAV route listed in this document would be published subsequently in FAA Order JO 7400.11F.

Differences From the NPRM

Subsequent to the publication of the NPRM for Docket No. FAA–2021–0867 in the **Federal Register** (86 FR 59065; October 26, 2021), establishing United States Area Navigation (RNAV) route T–435 in the vicinity of Sand Point, AK, the FAA determined it was necessary to relocate the HOLIM waypoint (WP), to address instrument flight procedure concerns related to two points (*i.e.* fix, navigational aid, WPs) being located too close to one another. As a result, the latitude/long geographic coordinates for the HOLIM WP are changed from what was proposed in the NPRM. This change moves the WP by approximately 600-feet from the location as proposed in the NPRM. The regulatory text in this action incorporates this change.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by establishing RNAV route T–435 in the vicinity of Sand Point, AK in support of a large and comprehensive T-route modernization project for the state of Alaska.

The route is described below.

T–435: This action establishes T–435 extending between the HOLIM, AK, WP, over Sand Point, AK and the King Salmon, AK, (AKN) VHF Omnidirectional Range and Tactical Air Navigational System (VORTAC).

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

Regulatory Notices and Analyses

The FAA 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. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (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 determined that this airspace action of establishing RNAV

route T–435 in the vicinity of Sand Point, AK qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points), and paragraph 5–6.5i, which categorically excludes from further environmental review the establishment of new or revised air traffic control procedures conducted at 3,000 feet or more above ground level (AGL); procedures conducted below 3,000 feet AGL that do not cause traffic to be routinely routed over noise sensitive areas; modifications to currently approved procedures conducted below 3,000 feet AGL that do not significantly increase noise over noise sensitive areas; and increases in minimum altitudes and landing minima. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

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 JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T–435 HOLIM, AK TO KING SALMON, AK (AKN) [NEW]		
HOLIM, AK	WP	(Lat. 55°18′56.09″ N, long. 160°30′55.56″ W)
RAYMD, AK	WP	(Lat. 55°35′53.52″ N, long. 160°12′33.45″ W)
FEPAB, AK	WP	(Lat. 56°21′10.67″ N, long. 159°30′57.40″ W)
WIXER, AK	WP	(Lat. 56°54′29.00″ N, long. 158°36′10.00″ W)
OBUKE, AK	FIX	(Lat. 57°28′55.62″ N, long. 158°07′01.03″ W)
King Salmon, AK (AKN)	VORTAC	(Lat. 58°43′28.97″ N, long. 156°45′08.45″ W)

* * * * *

Issued in Washington, DC, on June 22, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–13682 Filed 6–27–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0854; Airspace Docket No. 20–AAL–54]

RIN 2120–AA66

Revocation of Colored Federal Airway Blue 25 (B–25); Gulkana, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action revokes Colored Federal airway Blue 25 (B–25) in the vicinity of Gulkana, AK due to the decommissioning of the Glenallen, AK, (GLA) Non-Directional Beacon (NDB).

DATES: Effective date 0901 UTC, September 8, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, 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 Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jesse Acevedo, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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 the 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 modifies the air traffic service route structure in the north central United States to maintain the efficient flow of air traffic.

History

The FAA published a notice of proposed rulemaking for Docket No. FAA 2021–0854 in the **Federal Register** (86 FR 58606; October 22, 2021), revoking Colored Federal airway B–25, due to the decommissioning of the Glenallen, AK, (GLA) NDB. Interested parties were invited to participate in this rulemaking effort by submitting comments on the proposal. No comments were received.

Colored Federal airways are published in paragraph 6009(d) of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Colored Federal airway

listed in this document will be removed from FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by revoking Colored Federal airway B–25 in the vicinity of Gulkana, AK due to the decommissioning of the Glenallen, AK, (GLA) NDB.

B–25: B–25 currently extends between the Orca Bay, AK, NDB and the Delta Junction, AK, NDB. The FAA is removing the entire route.

FAA Order JO 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. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (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 airspace action of revoking Colored Federal Airway B–25 qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points). As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

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 TRAFFICSERVICE 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 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6009(d) Colored Federal Airways.

* * * * *

B–25 [Remove]

* * * * *

Issued in Washington, DC, on June 22, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–13689 Filed 6–27–22; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–1079; Airspace Docket No. 21–ASO–15]

RIN 2120–AA66

Amendment and Removal of Air Traffic Service (ATS) Routes; Eastern United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends one jet route, and removes one jet route and one high altitude area navigation (RNAV) route in the eastern United States. These actions are in support of the VHF Omnidirectional Range (VOR) Minimum Operational Network (MON) to improve the efficiency of the National Airspace System (NAS) and reduce dependency on ground-based navigational systems.

DATES: Effective date 0901 UTC, September 8, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, 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 Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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 the 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 modify the route structure as necessary to preserve the safe and efficient flow of air traffic within the NAS.

History

The FAA published a notice of proposed rulemaking for Docket No. FAA–2021–1079 in the **Federal Register** (86 FR 70771; December 13, 2021), amending four jet routes, and removing one jet route and one high altitude area navigation (RNAV) route in the eastern United States. The description of jet route J–73 was inadvertently omitted from the NPRM. Therefore, the FAA published a supplemental notice of proposed rulemaking in the **Federal Register** (87 FR 10997; February 28, 2022) amending J–73. Interested parties were invited to participate in this rulemaking effort by submitting written comments on both NPRMs. No comments were received.

Jet routes are published in paragraph 2004, and United States area navigation routes (Q routes) are published in paragraph 2006, respectively, of FAA Order JO 7400.11F dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The jet routes and Q route listed in this document would be subsequently amended in, or removed from, FAA Order JO 7400.11

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Differences From the NPRM

The NPRM included the proposed amendment of jet routes J–20, J–41, and J–73. Subsequent to publication of the NPRM, the FAA determined that additional coordination was needed to develop the modifications to these routes. Therefore, J–20, J–41, and J–73 are removed from this rule. Any action on those routes is delayed to a later date. Routes J–31, J–69, and Q–63 will be amended or removed as published in the NPRM.

The Rule

The FAA is proposing an amendment to 14 CFR part 71 to amend jet route J–31, and to remove J–69, and high altitude RNAV route Q–63, in the eastern United States. This action supports the VOR MON program.

The proposed route changes are as follows:

J–31: J–31 currently extends from Leeville, LA, to Vulcan, AL. This action removes the segment from Meridian, MS, to Vulcan, AL. As amended, J–31 extends from Leeville, LA, to Meridian, MS.

J–69: J–69 currently extends from Semmes, AL to Vulcan, AL. The route is not required for air traffic control purposes. This action removes the entire route.

Q–63: Q–63 currently extends between the DOOGE, VA, waypoint (WP) and the HEVAN, IN, WP. The FAA is removing Q–63 because it was replaced by an extension of Q–93 (Docket No. 2021–0913; 87 FR 14396; March 15, 2022), effective on May 19, 2022.

FAA Order JO 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. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (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 of amending jet route J–31, and removing J–69 and Q–63, in the eastern United States qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points); and paragraph 5–6.5b, which categorically excludes from further environmental impact review ''Actions regarding establishment of jet routes and Federal airways (see 14 CFR 71.15, *Designation of jet routes and VOR Federal airways*) . . .''. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. The FAA has determined no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

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 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 71.1 of FAA Order JO 7400.11F Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 2004 Jet Routes.

* * * * *

J–31 [Amended]

From Leeville, LA; Harvey, LA; to Meridian, MS.

* * * * *

J–69 [Removed]

* * * * *

Paragraph 2006 United States Area Navigation Routes.

* * * * *

Q–63 [Removed]

* * * * *

Issued in Washington, DC, on June 21, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–13579 Filed 6–27–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0851; Airspace Docket No. 19–AAL–42]

RIN 2120–AA66

Establishment of United States Area Navigation (RNAV) Route T–373; Bethel, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes United States Area Navigation (RNAV) route T–373 in the vicinity of Bethel, AK in support of a large and comprehensive T-route modernization project for the state of Alaska.

DATES: Effective date 0901 UTC, September 8, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, 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 Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jesse Acevedo, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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 the 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 expands the availability of RNAV in Alaska and improve the efficient flow of air traffic within the National Airspace System by lessening the dependency on ground based navigation.

History

The FAA published a notice of proposed rulemaking for Docket No. FAA–2021–0851 in the **Federal Register** (86 FR 58604; October 22, 2021), establishing United States Area Navigation (RNAV) route T–373 in the vicinity of Bethel, AK in support of a large and comprehensive T-route modernization project for the state of Alaska. Interested parties were invited to participate in this rulemaking effort by submitting comments on the proposal. There were no comments received.

United States Area Navigation Routes are published in paragraph 6011 of FAA Order JO 7400.11F dated August 10, 2021 and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The RNAV route listed in this document would be published subsequently in FAA Order JO 7400.11F.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Differences From the NPRM

The NPRM with Docket No. FAA–2021–0851 in the **Federal Register** (86 FR 58604; October 22, 2021), in the proposal section, mistakenly identified the Dillingham, AK, (DLG) VHF Omnidirectional Range/Distance Measuring Equipment (VOR/DME) navigational aide as a waypoint (WP). This rule corrects this error.

The Rule

This action amends14 CFR part 71 by establishing RNAV route T–373 in the vicinity of Bethel, AK in support of a large and comprehensive T-route modernization project for the state of Alaska.

The route is described below.

T–373: This action establishes RNAV route T–373 between the KOWOK, AK, Fix northeast of the Dillingham, AK, (DLG) VOR/DME, and the WEREL, AK, WP which is the WP replacing the Anvik, AK, (ANV) Non-Directional Beacon.

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

Regulatory Notices and Analyses

The FAA 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. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (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 determined that this airspace action of establishing RNAV route T–373 in the vicinity of Bethel, AK qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points), and paragraph 5–6.5i, which categorically excludes from further environmental review the establishment of new or revised air traffic control procedures conducted at 3,000 feet or more above ground level (AGL); procedures conducted below 3,000 feet AGL that do not cause traffic to be routinely routed over noise sensitive areas; modifications to

currently approved procedures conducted below 3,000 feet AGL that do not significantly increase noise over noise sensitive areas; and increases in minimum altitudes and landing minima. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

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 JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T–373 KOWOK, AK TO WEREL, AK [NEW]

KOWOK, AK	FIX	(Lat. 59°12′31.22″ N, long. 157°50′52.40″ W)
RAGES, AK	FIX	(Lat. 59°21′43.36″ N, long. 158°12′22.14″ W)
ZUDSO, AK	WP	(Lat. 59°48′13.53″ N, long. 158°57′43.10″ W)
MAYHW, AK	WP	(Lat. 59°48′11.94″ N, long. 159°16′08.97″ W)
FEXOP, AK	WP	(Lat. 60°15′14.46″ N, long. 160°07′38.69″ W)
Bethel, AK (BET)	VORTAC	(Lat. 60°47′05.41″ N, long. 161°49′27.59″ W)
WEREL, AK	WP	(Lat. 62°38′29.25″ N, long. 160°11′07.20″ W)

* * * * *

Issued in Washington, DC, on June 22, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–13683 Filed 6–27–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0308; Airspace Docket No. 22–AGL–18]

RIN 2120–AA66

Amendment of Class E Airspace; Mosinee, WI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace at Mosinee, WI. The FAA is taking this action due to an airspace review conducted as part of the decommissioning of the Wausau very high frequency (VHF) omnidirectional range (VOR) as part of the VOR Minimal Operational Network (MON) Program.

DATES: Effective 0901 UTC, September 8, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, 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.

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 E airspace extending upward from 700 feet above the surface at Central Wisconsin Airport, Mosinee, WI, to support instrument flight rule operations at this airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (87 FR 21067; April 11, 2022) for Docket No. FAA–2022–0308 to amend the Class E airspace at Mosinee, WI. 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 E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Differences From the NPRM

Subsequent to publication of the NPRM the FAA discovered that the geographic coordinates for the Central Wisconsin: RWY 08–LOC were incorrect. ''(lat. 44°47′07″ N, long. 89°28′30″ W)'' has been corrected to ''(lat. 44°47′07″ N, long. 89°38′30″ W).'' This correction has been incorporated into this action.

The Rule

This amendment to 14 CFR part 71 amends the Class E airspace extending upward from 700 feet above the surface at Central Wisconsin Airport, Mosinee, WI, by removing the Wausau VORTAC from the airspace legal description; adds an extension 1 mile each side of the 170° bearing from the Central Wisconsin: RWY 35–LOC extending from the 7-mile radius from the airport to 11.2 miles south of the airport; adds an extension 1 mile each side of the 257° bearing from the Central Wisconsin: RWY 08–LOC extending from the 7-mile radius of the airport to 11.5 miles west of the airport; and removes the extension north of the airport as the amended extension would be contained within the Wausau, WI, Class E airspace so would be redundant.

This action is due to an airspace review conducted as part of the decommissioning of the Wausau VOR, which provided navigation information for the instrument procedures at this airport, as part of the VOR MON Program.

FAA Order JO 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 JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

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

* * * * *

AGL WI E5 Mosinee, WI [Amended]

Central Wisconsin Airport, WI
(Lat. 44°46′39″ N, long. 89°40′00″ W)
Central Wisconsin: RWY 35–LOC
(Lat. 44°47′02″ N, long. 89°40′34″ W)
Central Wisconsin: RWY 08–LOC
(Lat. 44°47′07″ N, long. 89°38′30″ W)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of the Central Wisconsin Airport, and within 1 mile each side of the 170° bearing from the Central Wisconsin: RWY 35–LOC extending from the 7-mile radius of the airport to 11.2 miles south of the airport, and within 1 mile each side of the 257° bearing from the Central Wisconsin: RWY 08–LOC extending from the 7-mile radius of the airport to 11.5 miles west of the airport.

Issued in Fort Worth, Texas, on June 21, 2022.

Wayne L. Eckenrode,

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

[FR Doc. 2022–13569 Filed 6–27–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–1082; Airspace Docket No. 21–ASO–16]

RIN 2120–AA66

Amendment and Removal of Air Traffic Service (ATS) Routes; Eastern United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends jet routes J–22, and J–48; and removing jet routes J–39, J–118, J–145, and J–186 in the eastern United States. This action supports the VHF Omnidirectional Range (VOR) Minimum Operational Network (MON) program to improve the efficiency of the National Airspace System (NAS) and reduce dependency on ground-based navigational systems.

DATES: Effective date 0901 UTC, September 8, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, 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 Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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 the 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 modify the route structure as necessary to preserve the safe and efficient flow of air traffic within the NAS.

History

The FAA published a notice of proposed rulemaking for Docket No. FAA–2021–1082 in the **Federal Register** (86 FR 70778; December 13, 2021), amending three jet routes and removing four jet routes in the eastern United States. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. No comments were received.

Jet routes are published in paragraph 2004 of FAA Order JO 7400.11F dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The jet routes listed in this document would be subsequently amended in, or removed from, respectively, FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Difference From the NPRM

In the NPRM, the FAA proposed to amend jet route J–46. Subsequent to the publication of the NPRM, the FAA determined that additional coordination was needed to finalize the design of J–46. Consequently, J–46 is removed from this rule and will remain as currently shown on the IFR En Route chart. Any future modification of J–46 will be addressed in a separate rulemaking action. Routes J–22, J–48, J–39, J–118, J–145, and J–186 will be amended or removed by this rule as proposed in the NPRM.

The Rule

This action amends 14 CFR part 71 by amending jet routes J–22, and J–48; and removing jet routes J–39, J–118, J–145, and J–186 in the eastern United States. This action supports the VOR MON program by amending or removing certain jet route segments due to the planned decommissioning of ground-based navigation aids. Additionally, the jet route changes reduce aeronautical chart clutter by removing unneeded route segments.

The route changes are as follows:

J–22: J–22 currently extends from Nuevo Laredo, Mexico, to Montebello, VA. This action removes the route segments from Vulcan, AL, to Montebello, VA. As amended, the J–22 extends from Nuevo Laredo, Mexico to Meridian, MS. The portion within Mexico is excluded.

J–39: J–39 currently extends from Montgomery, AL, to Rosewood, OH. The FAA is removing the entire route.

J–48: J–48 currently extends from the intersection of the Solberg, NJ, 264° and the Pottstown, PA, 050° radials, to Foothills, SC. This action removes the segment between Montebello, VA, and Foothills, SC. As amended, J–48 extends from the intersection of the above Solberg and Pottstown radials to Montebello, VA.

J–118: J–118 currently extends from Memphis, TN, to Spartanburg, SC. The FAA is removing the entire route.

J–145: J–145 currently extends from Foothills, SC, to Charleston, WV. The FAA is removing the entire route.

J–186: J–186 currently extends from Foothills, SC, to Appleton, OH. The FAA is removing the entire route.

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. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (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 of amending jet routes J–22, and J–48; and removing jet routes J–39, J–118, J–145, and J–186 in the eastern United States qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points); and paragraph 5–6.5b, which categorically excludes from further environmental impact review ''Actions regarding establishment of jet routes and Federal airways (see 14 CFR 71.15, *Designation of jet routes and VOR Federal airways*) . . .''. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. The FAA has determined no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

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 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 71.1 of FAA Order JO 7400.11F Airspace Designations and Reporting Points, dated August 10, 2021, and

effective September 15, 2021, is amended as follows:

Paragraph 2004 Jet Routes.

* * * * *

J–22 [Amended]

From Nuevo Laredo, Mexico, via Laredo, TX; Corpus Christi, TX; Palacios, TX; Lake Charles, LA; McComb, MS; to Meridian, MS. The airspace within Mexico is excluded.

* * * * *

J–39 [Removed]

* * * * *

J–48 [Amended]

From INT Solberg, NJ, 264° and Pottstown, PA, 050° radials; Pottstown; Westminster, MD; Casanova, VA; to Montebello, VA.

* * * * *

J–118 [Removed]

* * * * *

J–145 [Removed]

* * * * *

J–186 [Removed]

* * * * *

Issued in Washington, DC.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–13583 Filed 6–27–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0818; Airspace Docket No. 19–AAL–35]

RIN 2120–AA66

Establishment of United States Area Navigation (RNAV) Route T–366; Point Hope, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes United States Area Navigation (RNAV) route T–366 in the vicinity of Point Hope, AK in support of a large and comprehensive T-route modernization project for the state of Alaska.

DATES: Effective date 0901 UTC, September 8, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, 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 Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jesse Acevedo, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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 the 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 expand the availability of RNAV in Alaska and improve the efficient flow of air traffic within the National Airspace System by lessening the dependency on ground based navigation.

History

The FAA published a notice of proposed rulemaking for Docket No. FAA–2021–0818 in the **Federal Register** (86 FR 58230; October 21, 2021), proposing to establish RNAV T-route, T–366 in the vicinity of Point Hope, AK in support of a large and comprehensive T-route modernization project for the state of Alaska. Interested parties were invited to participate in this rulemaking effort by submitting comments on the proposal. There were no comments received.

United States Area Navigation Routes are published in paragraph 6011 of FAA Order JO 7400.11F dated August 10, 2021 and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The RNAV route listed in this document will be published subsequently in FAA Order JO 7400.11F.

Differences From the NPRM

Subsequent to the publication of the NPRM for Docket No. FAA–2021–0818 in the **Federal Register** (86 FR 58230; October 21, 2021), the FAA determined it was necessary to relocate the following waypoints (WPs): VANTY, CABGI, JOGDU, and JATIL, to address instrument flight procedure concerns related to the WPs being located too close to the Non-Directional Beacon (NDB). As a result, the latitude/long geographic coordinates for the WPs are changed from what was proposed in the NPRM. This change will move each WP by approximately 600-feet from the location as proposed in the NPRM. The regulatory text in this action incorporates these changes.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by establishing RNAV route T–366 in the vicinity of Point Hope, AK in support of a large and comprehensive T-route modernization project for the state of Alaska.

The route is described below.

T–366: This action establishes T–366 navigating from the Point Hope, AK, (PHO) NDB to the Cape Lisburne, AK, (LUR) NDB using the VANTY, AK, WP and the CABGI, AK, WP, mirroring Colored airway B–5; from the Cape Lisburne, AK, (LUR) NDB to the Point Lay, AK, (PIZ) NDB, using the CABGI, AK,WP; the SUPGY, AK, WP; and the JODGU, AK, WP, mirroring Colored airway B–2; and from the Point Lay, AK, (PIZ) NDB to the Nuiqsut Village, AK, (UQS) NDB, using the JODGU, AK, WP; the FILEV, AK, WP; the Barrow, AK, VHF Omnidirectional Range/Distance Measuring Equipment (VOR/DME), and the JATIL, AK, WP, mirroring Colored airway G–16.

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

Regulatory Notices and Analyses

The FAA 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. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of

Transportation (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 determined that this airspace action of establishing RNAV route T–366 in the vicinity of Point Hope, AK qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points), and paragraph 5–6.5i, which categorically excludes from further environmental review the establishment of new or revised air traffic control procedures conducted at 3,000 feet or more above ground level (AGL); procedures conducted below 3,000 feet AGL that do not cause traffic to be routinely routed over noise sensitive areas; modifications to currently approved procedures conducted below 3,000 feet AGL that do not significantly increase noise over noise sensitive areas; and increases in minimum altitudes and landing minima. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. The FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

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 JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T–366 VANTY, AK to JATIL, AK [New]

VANTY, AK	WP	(Lat. 68°20′40.64″ N, long. 166°48′09.96″ W)
CABGI, AK	WP	(Lat. 68°52′16.94″ N, long. 166°04′50.37″ W)
SUPGY, AK	WP	(Lat. 69°01′57.87″ N, long. 164°13′31.71″ W)
JODGU, AK	WP	(Lat. 69°44′11.47″ N, long. 163°00′04.08″ W)
FILEV, AK	WP	(Lat. 70°38′16.81″ N, long. 159°59′41.10″ W)
Barrow, AK (BRW)	VOR/DME	(Lat. 71°16′24.33″ N, long. 156°47′17.22″ W)
JATIL, AK	WP	(Lat. 70°12′46.02″ N, long. 151°00′19.83″ W)

* * * * *

Issued in Washington, DC, on June 22, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–13688 Filed 6–27–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0456; Airspace Docket No. 21–ASO–34]

RIN 2120–AA66

Amendment of Area Navigation (RNAV) Route Q–75; Eastern United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Area Navigation (RNAV) route Q–75 to resolve similar sounding waypoint (WP) names and removes WPs and fixes that are not required for defining the route structure. Q–75 supports the Northeast Corridor Atlantic Coast Route Project.

DATES: Effective date 0901 UTC, September 8, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, 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 Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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 the 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 modifies the route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System.

History

The FAA published a notice of proposed rulemaking for Docket No. FAA–2022–0456, in the **Federal Register** (87 FR 25159; April 28, 2022), amending RNAV route Q–75.

Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. Two comments were received.

RNAV routes are published in paragraph 2006 of FAA Order JO 7400.11F dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The RNAV routes listed in this document would be subsequently published in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Discussion of Comment

One commenter wrote in support of renaming the DUEYS, NY, Fix as the FARLE, NY, Fix. But, the commenter objected to the proposed removal of 11 fixes and WPs from the route legal description. The commenter believes that all points depicted on IFR En Route charts should be included in the regulatory description of the route.

The FAA does not agree. The part 71 legal description contains the points necessary to define the alignment of the route. These points consist of: the beginning and end points of the route; points where the route changes direction; holding fixes; and points required due to the maximum distance allowed between navigation aids, fixes, or WPs. The points being removed from the part 71 Q–75 legal description do not serve any of those purposes. However, they are still contained in the National Airspace System Resources Database and will continue to be depicted on the IFR En Route charts.

Another commenter asked about the financial cost of making the proposed changes to the route. The proposed WP name change is made to resolve a potential safety issue of misinterpreting similar sounding names during radio communications. This is an editorial change that is covered under the routine maintenance of the currency of aeronautical charts. These charts are published every 56 days. The points being removed are removed from the Q–75 14 CFR part 71 legal description only. Points that do not mark a turn point on a route are not required in the part 71 legal description. However, in this case, the points will still be maintained in the airspace data base, and will remain as currently shown on the IFR chart. Therefore, there is no cost involved in removing the points from the legal description.

The Rule

This action amends 14 CFR part 71 by amending RNAV route Q–75 as described below.

Q–75: Q–75 currently extends from the ENEME, GA, WP to the COPLY, MA, WP. This rule replaces the name ''DUEYS, NY, Fix'' with the name ''FARLE, NY, Fix'' for safety reasons. The current DUEYS Fix is located just 2.45 nautical miles from the DEEZZ, NY, Fix (which is located adjacent to, but not on, Q–75). The similar sounding pronunciation of the two fixes can lead to pilot/air traffic controller miscommunication. The latitude/longitude coordinates of the FARLE Fix remain the same as used for the DUEYS Fix, therefore this change does not affect the current charted alignment of Q–75. In addition, the FAA is removing a number of WPs and fixes from the description of Q–75, because they do not denote a route turn point and they are not required to be included in the Q–75 part 71 description. However, these points will continue to be depicted on the IFR En Route charts because they are used for air traffic control purposes. The affected WPs and fixes are: TEUFL, GA, WP; BROSK, NC, WP; DRAIK, VA, Fix; TOOBN, MD, WP; SACRI, MD, Fix; STOEN, PA, Fix; COPES, PA, Fix; BIGGY, NJ, Fix; JERSY, NJ, Fix; GREKI, CT, Fix; and SWALO, MA, Fix.

The full route description of Q–75 is listed in ''The Amendment'' section, below.

FAA Order JO 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. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (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 of amending RNAV route Q–75 qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points); and paragraph 5–6.5b, which categorically excludes from further environmental impact review ''Actions regarding establishment of jet routes and Federal airways (see 14 CFR 71.15, *Designation of jet routes and VOR Federal airways*) . . .''. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

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 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 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 2006 United States Area Navigation Routes.

* * * * *

Q–75 ENEME, GA TO COPLY, MA [AMENDED]

ENEME, GA	WP	(Lat. 30°42′12.09″ N, long. 082°26′09.31″ W)
TEEEM, GA	WP	(Lat. 32°08′41.20″ N, long. 081°54′50.57″ W)
SHRIL, GA	WP	(Lat. 32°54′42.21″ N, long. 081°34′09.78″ W)
FISHO, SC	WP	(Lat. 33°16′46.25″ N, long. 081°24′43.52″ W)
ILBEE, SC	WP	(Lat. 34°18′41.66″ N, long. 081°01′07.88″ W)
SLOJO, SC	WP	(Lat. 34°38′46.31″ N, long. 080°39′25.63″ W)
Greensboro, NC (GSO)	VORTAC	(Lat. 36°02′44.49″ N, long. 079°58′34.95″ W)
Gordonsville, VA (GVE)	VORTAC	(Lat. 38°00′48.96″ N, long. 078°09′10.90″ W)
HAMMZ, VA	WP	(Lat. 38°43′51.56″ N, long. 077°19′59.85″ W)
MURPH, MD	FIX	(Lat. 39°27′51.22″ N, long. 076°23′07.24″ W)
Modena, PA (MXE)	VORTAC	(Lat. 39°55′05.00″ N, long. 075°40′14.96″ W)
Solberg, NJ (SBJ)	VOR/DME	(Lat. 40°34′58.95″ N, long. 074°44′30.45″ W)
FARLE, NY	WP	(Lat. 41°09′09.46″ N, long. 073°47′48.52″ W)
BIZEX, NY	WP	(Lat. 41°17′02.86″ N, long. 073°34′50.20″ W)
NELIE, CT	FIX	(Lat. 41°56′27.64″ N, long. 072°41′18.88″ W)
Boston, MA (BOS)	VOR/DME	(Lat. 42°21′26.82″ N, long. 070°59′22.37″ W)
COPLY, MA	WP	(Lat. 42°29′52.21″ N, long. 070°33′28.57″ W)

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Issued in Washington, DC, on June 21, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–13580 Filed 6–27–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0626; Airspace Docket No. 22–ASO–8]

RIN 2120–AA66

Amendment and Removal of Area Navigation (RNAV) Routes; South-Central Florida Metroplex Project

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends low altitude United States Area Navigation (RNAV) routes, T–207, T–210, T–336, T–339, T–341, T–343, T–345, T–347, T–349, and T–353; and removes T–337, in support of the South-Central Florida Metroplex Project. These route changes were previously proposed in Docket No. FAA–2021–0940 but were deferred to a later date due to additional planning and coordination requirements.

DATES: Effective date 0901 UTC, September 8, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, 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 Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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 the 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 modifies the route structure as necessary to preserve the safe and efficient flow of air traffic within the NAS.

History

The FAA published a notice of proposed rulemaking for Docket No. FAA–2021–0940, in the **Federal**

Register (86 FR 61724; November 8, 2021). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. No comments were received. However, the FAA determined that additional planning and coordination was required for the routes contained in this rule, so they were removed from the previous docket action. The route descriptions in this rule are as published in the NPRM.

United States RNAV T-routes are published in paragraph 6011 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The RNAV routes listed in this document will be subsequently published in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by amending RNAV T-routes T–207, T–210, T–336 T–339, T–341, T–343, T–345, T–347, T–349, and T–353; and removing T–337, in support of the South-Central Florida Metroplex Project. The route changes are described below.

T–207: T–207 currently extends between the Ormond Beach, FL, (OMN) VHF Omnidirectional Radar and Tactical Air Navigational System (VORTAC) and the Waycross, GA, (AYS) VORTAC. This action realigns T–207 by moving the starting point from the Ormond Beach VORTAC to the FOXAM, FL, waypoint (WP), which is approximately 15 nautical miles (NM) north of the Ormond Beach VORTAC. The CARRA, FL, Fix and the MONIA, FL, Fix are removed from the route, and the segments between the CARRA Fix and the Waycross, GA, (AYS) VORTAC are also removed. Instead, T–207 begins at the FOXAM, FL, WP, then proceeds to the MMKAY, FL WP, then to a new end point at the WALEE, FL, WP (located east of the Gators, FL, (GNV) VORTAC).

T–210: T–210 currently extends between the MARQO, FL, WP, and the VARZE, FL, WP. The MARQO, FL, WP, and the BRADO, FL, Fix are removed from the route. The start point of the route is moved to the HADDE, FL, Fix, which is approximately 35 NM west of the MARQO, FL, WP. The MISSM, FL, WP is added between the HADDE, FL, Fix and the OHLEE, FL, WP. After the OHLEE, FL, WP, the route proceeds to the MMKAY, FL, WP, and then southward to the VARZE, FL, WP, as currently charted.

T–336: T–336 currently extends between the TROYR, FL, WP, and the WIXED, FL, WP. The FAA is amending the route by adding the FUTSY, FL, WP between the TROYR, FL, and OMMNI, FL, WPs. The VISTA, FL, WP is added between the OMMNI, FL, WP and the PUNQU, FL WP. The WIXED, FL, WP (the current end point of the route) is removed from T–336. A new end point for the route is established at the VALKA, FL, Fix. The VALKA Fix is approximately 15 NM northwest of the WIXED WP. As amended, T–336 extends between the TROYR, FL, WP, and the VALKA, FL, Fix.

T–337: T–337 currently extends between the SWENY, FL, WP and the WEZER, FL, WP. T–337 no longer provides the most efficient route into or out of southwest FL, therefore, the FAA is removing the entire route.

T–339: T–339 currently extends between the KARTR, FL, Fix and the ODDEL, FL, Fix. This change removes the KARTR Fix from the route. The start point is moved approximately 25 NM to the southeast of the KARTR Fix to the existing CARNU, FL, Fix. From the CARNU Fix, T–339 proceeds to the DEEDS, FL, Fix, and then proceeds to the end point at the ODDEL, FL, Fix as currently charted.

T–341: T–341 currently extends between the MEAGN, FL, WP, and the MARQO, FL WP. The FAA is inserting additional WPs along the route as follows. The YELLZ, FL, WP is inserted between the CUSEK, FL, WP and the WEZER, FL, WP. The DULFN, FL; OMMNI, FL; and WHOOU, FL, WPs are added between the VARSE, FL, and the MARQO, FL, WPs.

T–343: T–343 currently extends between the WORPP, FL, Fix, and the INDIA, FL, Fix. The WORPP Fix is removed from the route and the COOFS, FL, Fix becomes the new start point for the route. The COOFS Fix is approximately 2 NM southwest of the WORPP Fix.

T–345: T–345 currently extends between the MARKT, FL WP, and the DEARY, FL, Fix. The only change to the route is removing the DEARY, FL, Fix as the end point and substituting the VALKA, FL, Fix as the new end point. This realigns the route between the LLNCH, FL, Fix and the VALKA, FL, Fix to the east of its current track.

T–347: T–347 currently extends between the CLEFF, FL, WP, and the SEBAG, FL, Fix. This action moves the start point from the CLEFF, FL, WP southward to the SHANC, FL, Fix. This change extends T–347 southward by approximately 50 NM increasing the availability of RNAV routing. In addition, the ODDEL, FL, Fix is added between the BAIRN, FL, Fix and the SABOT, FL, Fix. As amended, T–347 extends between the SHANC, FL, Fix and the SEBAG, FL, Fix.

T–349: T–349 currently extends between the VARSE, FL, WP, and the TROYR, FL, WP. The only change to this route is the addition of the MILOW, FL, WP, and the MURDE, FL, WP between the VARSE, FL, WP and the TROYR, FL WP. The alignment of T–349 is not affected by this change.

T–353: T–353 currently extends between the FEBRO, FL, WP and the ASTOR, FL, Fix. This action removes the ASTOR, FL, Fix from the route and establishes a new end point for the route at the STARY, GA, Fix (located 18 NM northeast of the Brunswick, GA, (SSI) VORTAC. The COBOK, FL, Fix and the SUBER, FL, Fix are added between the FOXAM, FL, WP, and the STARY, GA, Fix. This results in the track of T–353 north of the FOXAM WP being shifted to the east of its current alignment. Additionally, moving the end point of the route from the ASTOR Fix to the STARY Fix provides approximately 80 NM of additional RNAV routing in the NAS.

FAA Order JO 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. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (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 of amending 10 low altitude United States Area Navigation (RNAV) T routes, and removing one T route, as described above, in support of efforts transitioning the NAS from ground-based to satellite-based navigation, qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points); and paragraph 5–6.5b, which categorically excludes from further environmental impact review ''Actions regarding establishment of jet routes and Federal airways (see 14 CFR 71.15, *Designation of jet routes and VOR Federal airways*) . . .''. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

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 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 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T–207 FOXAM, FL to WALEE, FL [Amended]

FOXAM, FL	WP	(Lat. 29°33′37.73″ N, long. 081°09′37.84″ W)
MMKAY, FL	WP	(Lat. 29°41′55.42″ N, long. 081°26′49.15″ W)
WALEE, FL	WP	(Lat. 29°41′36.05″ N, long. 082°14′07.07″ W)

* * * * * * *

T–210 HADDE, FL to VARZE, FL [Amended]

HADDE, FL	FIX	(Lat. 30°31′54.46″ N, long. 083°13′50.21″ W)
MISSM, FL	WP	(Lat. 30°27′28.15″ N, long. 082°36′32.24″ W)
OHLEE, FL	WP	(Lat. 30°16′06.04″ N, long. 082°06′32.53″ W)
MMKAY, FL	WP	(Lat. 29°41′55.42″ N, long. 081°26′49.15″ W)
MRUTT, FL	WP	(Lat. 29°12′12.40″ N, long. 081°23′55.50″ W)
GUANO, FL	FIX	(Lat. 29°05′58.73″ N, long. 081°23′18.93″ W)
KIZER, FL	FIX	(Lat. 28°55′26.00″ N, long. 081°22′17.83″ W)
EMSEE, FL	WP	(Lat. 28°50′43.72″ N, long. 081°32′47.03″ W)
DAIYL, FL	WP	(Lat. 28°49′10.74″ N, long. 081°41′29.68″ W)
AKOJO, FL	WP	(Lat. 28°45′44.01″ N, long. 081°43′31.54″ W)
PUNQU, FL	WP	(Lat. 28°34′33.65″ N, long. 081°49′22.43″ W)
VARZE, FL	WP	(Lat. 28°16′25.85″ N, long. 082°01′44.51″ W)

* * * * * * *

T–336 TROYR, FL to VALKA, FL [Amended]

TROYR, FL	WP	(Lat. 29°34′20.92″ N, long. 083°01′52.68″ W)
FUTSY, FL	WP	(Lat. 29°06′46.70″ N, long. 082°28′11.29″ W)
OMMNI, FL	WP	(Lat. 28°51′29.29″ N, long. 082°09′41.75″ W)
VIZTA, FL	WP	(Lat. 28°45′18.38″ N, long. 082°02′15.09″ W)
PUNQU, FL	WP	(Lat. 28°34′33.65″ N, long. 081°49′22.43″ W)
YOJIX, FL	FIX	(Lat. 28°02′44.04″ N, long. 081°33′45.34″ W)
YONMA, FL	FIX	(Lat. 28°03′55.68″ N, long. 081°24′31.18″ W)
ODDEL, FL	FIX	(Lat. 28°05′45.51″ N, long. 081°10′10.24″ W)
DEARY, FL	FIX	(Lat. 28°06′02.53″ N, long. 080°54′51.40″ W)
VALKA, FL	FIX	(Lat. 27°55′06.06″ N, long. 080°34′17.17″ W)

* * * * * * *

T–337 SWENY, FL to WEZER, FL [Removed]

* * * * * * *

T–339 CARNU, FL to ODDEL, FL [Amended]

CARNU, FL	FIX	(Lat. 25°08′18.13″ N, long. 081°19′32.12″ W)
DEEDS, FL	FIX	(Lat. 25°58′40.31″ N, long. 081°13′59.60″ W)
SWAGS, FL	FIX	(Lat. 26°10′37.07″ N, long. 081°05′59.93″ W)
ZAGPO, FL	WP	(Lat. 26°23′47.41″ N, long. 080°57′25.83″ W)
DIDDY, FL	FIX	(Lat. 27°18′38.15″ N, long. 080°52′55.92″ W)
ODDEL, FL	FIX	(Lat. 28°05′45.51″ N, long. 081°10′10.24″ W)

* * * * * * *

T–341 MEAGN, FL to MARQO, FL [Amended]

MEAGN, FL	WP	(Lat. 26°14′17.20″ N, long. 080°47′23.64″ W)
ZAGPO, FL	WP	(Lat. 26°23′47.41″ N, long. 080°57′25.83″ W)
CUSEK, FL	WP	(Lat. 26°51′38.79″ N, long. 081°23′17.37″ W)
YELLZ, FL	WP	(Lat. 27°51′36.18″ N, long. 081°56′34.16″ W)

WEZER, FL	WP	(Lat. 28°02′26.59″ N, long. 082°02′39.60″ W)
VARZE, FL	WP	(Lat. 28°16′25.85″ N, long. 082°01′44.51″ W)
DULFN, FL	WP	(Lat. 28°37′02.05″ N, long. 082°06′24.33″ W)
OMMNI, FL	WP	(Lat. 28°51′29.29″ N, long. 082°09′41.75″ W)
WHOOU, FL	WP	(Lat. 29°51′25.91″ N, long. 082°23′30.65″ W)
MARQO, FL	WP	(Lat. 30°30′53.57″ N, long. 082°32′45.62″ W)

* * * * * * *

T–343 COOFS, FL to INDIA, FL [Amended]

COOFS, FL	FIX	(Lat. 25°52′18.17″ N, long. 081°00′37.52″ W)
CUSEK, FL	WP	(Lat. 26°51′38.79″ N, long. 081°23′17.37″ W)
FEBRO, FL	WP	(Lat. 27°37′02.08″ N, long. 081°47′07.68″ W)
TAHRS, FL	WP	(Lat. 27°52′12.96″ N, long. 081°33′55.12″ W)
YOJIX, FL	FIX	(Lat. 28°02′44.04″ N, long. 081°33′45.34″ W)
YONMA, FL	FIX	(Lat. 28°03′55.68″ N, long. 081°24′31.18″ W)
ODDEL, FL	FIX	(Lat. 28°05′45.51″ N, long. 081°10′10.24″ W)
DEARY, FL	FIX	(Lat. 28°06′02.53″ N, long. 080°54′51.40″ W)
INDIA, FL	FIX	(Lat. 28°26′04.19″ N, long. 080°45′55.25″ W)

* * * * * * *

T–345 MARKT, FL to VALKA, FL [Amended]

MARKT, FL	WP	(Lat. 26°22′53.63″ N, long. 080°34′41.82″ W)
AIRBT, FL	WP	(Lat. 26°46′51.62″ N, long. 080°42′21.85″ W)
DOWDI, FL	WP	(Lat. 27°07′16.35″ N, long. 080°42′02.47″ W)
LLNCH, FL	FIX	(Lat. 27°26′07.67″ N, long. 080°41′44.46″ W)
VALKA, FL	FIX	(Lat. 27°55′06.06″ N, long. 080°34′17.17″ W)

* * * * * * *

T–347 SHANC, FL to SEBAG, FL [Amended]

SHANC, FL	FIX	(Lat. 26°18′51.14″ N, long. 080°20′00.16″ W)
BOBOE, FL	WP	(Lat. 26°28′48.72″ N, long. 080°23′05.23″ W)
DURRY, FL	WP	(Lat. 26°43′46.96″ N, long. 080°24′09.25″ W)
CLEFF, FL	WP	(Lat. 27°00′03.31″ N, long. 080°32′38.27″ W)
BAIRN, FL	FIX	(Lat. 27°56′52.37″ N, long. 081°06′54.35″ W)
ODDEL, FL	FIX	(Lat. 28°05′45.51″ N, long. 081°10′10.24″ W)
SABOT, FL	FIX	(Lat. 28°15′05.10″ N, long. 081°13′37.16″ W)
CROPY, FL	FIX	(Lat. 28°47′32.71″ N, long. 081°21′35.38″ W)
KIZER, FL	FIX	(Lat. 28°55′26.00″ N, long. 081°22′17.83″ W)
GUANO, FL	FIX	(Lat. 29°05′58.73″ N, long. 081°23′18.93″ W)
MRUTT, FL	WP	(Lat. 29°12′12.40″ N, long. 081°23′55.50″ W)
FOXAM, FL	WP	(Lat. 29°33′37.73″ N, long. 081°09′37.84″ W)
SEBAG, FL	FIX	(Lat. 29°49′04.24″ N, long. 081°12′34.72″ W)

* * * * * * *

T–349 VARZE, FL to TROYR, FL [Amended]

VARZE, FL	WP	(Lat. 28°16′25.85″ N, long. 082°01′44.51″ W)
MILOW, FL	WP	(Lat. 28°38′02.43″ N, long. 082°18′14.27″ W)
MURDE, FL	WP	(Lat. 29°01′30.64″ N, long. 082°36′18.52″ W)
TROYR, FL	WP	(Lat. 29°34′20.92″ N, long. 083°01′52.68″ W)

* * * * * * *

T–353 FEBRO, FL to STARY, GA [Amended]

FEBRO, FL	WP	(Lat. 27°37′02.08″ N, long. 081°47′07.68″ W)
MOANS, FL	FIX	(Lat. 27°54′49.97″ N, long. 081°44′54.89″ W)
PUNQU, FL	WP	(Lat. 28°34′33.65″ N, long. 081°49′22.43″ W)
AKOJO, FL	WP	(Lat. 28°45′44.01″ N, long. 081°43′31.54″ W)
DAIYL, FL	WP	(Lat. 28°49′10.74″ N, long. 081°41′29.68″ W)
EMSEE, FL	WP	(Lat. 28°50′43.72″ N, long. 081°32′47.03″ W)
KIZER, FL	FIX	(Lat. 28°55′26.00″ N, long. 081°22′17.83″ W)
GUANO, FL	FIX	(Lat. 29°05′58.73″ N, long. 081°23′18.93″ W)
MRUTT, FL	WP	(Lat. 29°12′12.40″ N, long. 081°23′55.50″ W)
FOXAM, FL	WP	(Lat. 29°33′37.73″ N, long. 081°09′37.84″ W)
COBOK, FL	FIX	(Lat. 29°48′30.53″ N, long. 081°06′45.71″ W)
SUBER, FL	FIX	(Lat. 30°27′24.49″ N, long. 081°06′45.46″ W)
STARY, GA	FIX	(Lat. 31°12′04.70″ N, long. 081°08′40.48″ W)

* * * * * * *

Issued in Washington, DC, on June 21, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–13581 Filed 6–27–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2022–0264]

Safety Zones; Recurring Safety Zones in Captain of the Port Sault Sainte Marie Zone for Events Beginning in July 2022

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce established safety zones for maritime events in Sault Sainte Marie area listed in Table 1 of this document starting in July 2022. This action is necessary to provide for the safety of life on navigable waterways. During the enforcement periods, vessels must stay out of the established safety zone and may only enter with permission from the designated representative of the Captain of the Port Sault Sainte Marie.

DATES: The regulations in 33 CFR 165.918 will be enforced for the safety zones identified in Table 1 of the **SUPPLEMENTARY INFORMATION** section below for the dates and times specified.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email Waterways Management division, LT Deaven Palenzuela, Coast Guard Sector Sault Sainte Marie, U.S. Coast Guard; telephone 906–635–3223, email *ssmprevention@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zones defined in 33 CFR 165.918 as per the time, dates, and locations in Table 1.

TABLE 1

[Datum NAD 1983]

Event	Location	Event date
(5) National Cherry Festival Airshow Safety Zone; Traverse City, MI.	All U.S. navigable waters of the West Arm of Grand Traverse Bay within a box bounded by the following coordinates: 44°46′51.6″ N, 085°38′15.6″ W, 44°46′23.4″ N, 085°38′22.8″ W, 44°46′30″ N, 085°35′42″ W, and 44°46′2.34″ N, 085°35′50.4″ W.	Practice date: June 30, 2022, and July 1, 2022, from 12 noon through 4 p.m. Full Airshow dates: July 2–3, 2022, from 12 noon through 4 p.m.
(7) Canada Day Celebration Fireworks; Sault Sainte Marie, MI.	All U.S. navigable waters of the St. Mary's River within an approximate 1400-foot radius from the fireworks launch site, centered approximately 160 yards north of the U.S. Army Corp of Engineers Soo Locks Northeast Pier, at position 46°30′20.40″ N, 084°20′17.64″ W.	On July 1, 2022, from 9 p.m. through 12:01 a.m.
(8) Marquette Fourth of July Celebration Fireworks; Marquette, MI.	All U.S. navigable waters of Marquette Harbor within an approximate 1200-foot radius of the fireworks launch site, centered in position 46°32′23.0″ N, 087°23′13.1″ W.	On July 4, 2022, from 10 p.m. through 11:30 p.m.
(9) Munising Fourth of July Celebration Fireworks; Munising, MI.	All U.S. navigable waters of South Bay within an approximate 800-foot radius from the fireworks launch site at the end of the Munising City Dock, centered in position: 46°24′50.08″ N, 086°39′08.52″ W.	On July 4, 2022, from 7 p.m. through 11:30 p.m.
(10) Sault Sainte Marie Fourth of July Celebration Fireworks; Sault Sainte Marie, MI.	All U.S. navigable waters of the St. Mary's River within an approximate 1000-foot radius around the eastern portion of the U.S. Army Corp of Engineers Soo Locks Northeast Pier, centered in position: 46°30′19.66″ N, 084°20′31.61″ W.	On July 4, 2022, from 9 p.m. through 12:01 a.m. Rain date: July 5, 2022 from 9 p.m. through 12: 01 a.m.
(11) Mackinac Island Fourth of July Celebration Fireworks; Mackinac Island, MI.	All U.S. navigable waters of Lake Huron within an approximate 750-foot radius of the fireworks launch site, centered in position 45°50′34.92″ N, 084°37′38.16″ W.	On July 4, 2022, from 9 p.m. through 12:01 a.m.
(12) Harbor Springs Fourth of July Celebration Fireworks; Harbor Springs, MI.	All U.S. navigable waters of Lake Michigan and Harbor Springs Harbor within the arc of a circle with an approximate 1200-foot radius from the fireworks launch site located on a barge in position 45°25′30″ N, 084°59′06″ W.	On July 4, 2022, from 9:15 p.m. through 11:45 p.m.
(13) Bay Harbor Yacht Club Fourth of July Celebration Fireworks; Petoskey, MI.	All U.S. navigable waters of Lake Michigan and Bay Harbor Lake within the arc of a circle with an approximate 750-foot radius from the fireworks launch site located on a barge in position 45°21′50″ N, 085°01′37″ W.	On July 3, 2022, from 10:15 p.m. through 10:45 p.m.

TABLE 1—Continued
[Datum NAD 1983]

Event	Location	Event date
(14) Petoskey Fourth of July Celebration Fireworks; Petoskey, MI.	All U.S. navigable waters of Lake Michigan and Petoskey Harbor, in the vicinity of Bay Front Park, within the arc of a circle with an approximate 1200-foot radius from the fireworks launch site located in position 45°22′40″ N, 084°57′30″ W.	On July 4, 2022, from 9 p.m. through 12:01 a.m.
(15) Boyne City Fourth of July Celebration Fireworks; Boyne City, MI.	All U.S. navigable waters of Lake Charlevoix, in the vicinity of Veterans Park, within the arc of a circle with an approximate 1400-foot radius from the fireworks launch site located in position 45°13′30″ N, 085°01′40″ W.	On July 4, 2022, from 6 p.m. through 11 p.m.
(16) Alpena Fourth of July Celebration Fireworks; Alpena, MI.	All U.S. navigable waters of Lake Huron within an approximate 1000-foot radius of the fireworks launch site located near the end of Mason Street, South of State Avenue, at position 45°02′42″ N, 083°26′48″ W.	On July 4, 2022, from 9 p.m. through 11 p.m.
(17) Traverse City Fourth of July Celebration Fireworks; Traverse City, MI.	All U.S. navigable waters of the West Arm of Grand Traverse Bay within the arc of a circle with an approximate 1200-foot radius from the fireworks launch site located on a barge in position 44°46′12″ N, 085°37′06″ W.	On July 4, 2022, from 9 p.m. through 11:30 p.m. Rain date: July 5, 2022 from 9 p.m. through 11:30 p.m.
(18) Charlevoix Venetian Festival Friday Night Fireworks; Charlevoix, MI.	All U.S. navigable waters of Lake Charlevoix, in the vicinity of Depot Beach, within the arc of a circle with an approximate 1200-foot radius from the fireworks launch site located on a barge in position 45°19′08″ N, 085°14′18″ W.	On July 22, 2022, from 9 p.m. through 12:01 a.m.
(19) Charlevoix Venetian Saturday Night Fireworks; Charlevoix, MI.	All U.S. navigable waters of Round Lake within the arc of a circle with an approximate 250-foot radius from the fireworks launch site located on a barge in position 45°19′03″ N, 085°15′18″ W.	On July 23, 2022, from 9 p.m. through 12:01 a.m.

This action is necessary for the safety of life on navigable waterways during the fireworks displays. The regulations found in 33 CFR 165.918 for safety zones listed in Table 1 within the Captain of the Port Sault Sainte Marie Zone apply for these fireworks displays.

This notification of enforcement is issued under authority of 33 CFR 165.918 and 5 U.S.C. 552(a). In addition to this notification of enforcement in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via Broadcast Notice to Mariners or Local Notice to Mariners. If the Captain of the Port Sault Sainte Marie determines that the safety zone need not be enforced for the full duration stated in this notification, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the respective safety zone.

Dated: June 22, 2022.

A.R. Jones,

Captain, U.S. Coast Guard, Captain of the Port Sault Sainte Marie.

[FR Doc. 2022–13677 Filed 6–27–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2022–0265]

Safety Zones; Recurring Safety Zones in Captain of the Port Sault Sainte Marie Zone for Events Beginning in August 2022

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce established safety zones in the Sault Sainte Marie area listed in Table 1 of this document for maritime events starting in August 2022. This action is necessary and intended to protect the safety of life on navigable waterways. During the enforcement periods, vessels must stay out of the established safety zones and may only enter with permission from the designated representative of the Captain of the Port Sault Sainte Marie.

DATES: The regulations listed in 33 CFR 165.918 will be enforced for the safety zones identified in Table 1 of the **SUPPLEMENTARY INFORMATION** section below for the dates and times specified.

FOR FURTHER INFORMATION CONTACT: If you have questions about this publication, call or email LT Deaven Palenzuela, Waterways Management division, Coast Guard Sector Sault Sainte Marie, U.S. Coast Guard; telephone 906–635–3223, email *ssmprevention@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zones in 33 CFR 165.918 as per the time, dates, and locations in Table 1.

TABLE 1
[Datum NAD 1983]

Event	Location	Event date
(20) Elk Rapids Harbor Days Fireworks; Elk Rapids, MI.	All U.S. navigable waters within the arc of a circle with an approximate 500-foot radius from the fireworks launch site located on a barge in position 44°54′6.95″ N, 85°25′3.11″ W.	On August 6, 2022, from 10 p.m. through 10:30 p.m.
(21) Nautical City Fireworks, Rogers City.	All U.S. navigable waters within the arc of a circle with an approximate 750-foot radius from the fireworks launch site located near Harbor View Road in position 45°24′59.07.72″ N, 083°47′50.57″ W.	On August 7, 2022, from 10 p.m. through 10:30 p.m.

This action is being taken to provide for the safety of life on navigable waterways during the fireworks displays. The regulations for safety zones within the Captain of the Port Sault Sainte Marie Zone, § 165.918, apply for these fireworks displays.

This notification of enforcement is issued under authority of 33 CFR 165.918 and 5 U.S.C. 552(a). In addition to this notification of enforcement in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via Broadcast Notice to Mariners or Local Notice to Mariners. If the Captain of the Port Sault Sainte Marie determines that the safety zone need not be enforced for the full duration stated in this notification, he may use a Broadcast Notice to Mariners to grant general permission to enter the respective safety zone.

Dated: June 22, 2022.

A.R. Jones,

Captain, U.S. Coast Guard, Captain of the Port Sault Sainte Marie.

[FR Doc. 2022–13679 Filed 6–27–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2022–0516]

RIN 1625–AA00

Safety Zone; Mackinac Island 4th of July Celebration Fireworks, Lake Huron, Mackinac Island, MI

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters within a 750-foot radius of a fireworks display in Lake Huron near Mackinac Island, MI. The safety zone is necessary to protect personnel, vessels, and the marine environment from potential hazards created by the fireworks display. Entry of vessels or persons into this safety zone is prohibited unless specifically authorized by the Captain of the Port Sault Sainte Marie or his designated representative.

DATES: This rule is effective from 9 p.m. through 12:01 a.m. on July 4, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2022–0516 in the ''SEARCH'' box and click ''SEARCH.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LT Deaven Palenzuela, U.S. Coast Guard Sector Sault Sainte Marie Waterways Management, U.S. Coast Guard; telephone 906–635–3223, email *ssmprevention@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable. The Coast Guard did not receive sufficient notice of this event to undergo notice and comment and this safety zone must be established by July 4, 2022, in order to protect the public from the dangers associated with the fireworks display.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable as immediate action is necessary to protect against the potential safety hazards associated with the fireworks display.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Sault Sainte Marie (COTP) has determined that potential hazards associated with the fireworks display on July 4, 2022, would be a safety concern for anyone within the safety zone. This rule is necessary to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone during the fireworks display.

IV. Discussion of the Rule

This rule establishes a safety zone from 9 p.m. through 12:01 a.m. on July 4, 2022. The safety zone will cover all navigable waters within 750 feet of a fireworks display in Lake Huron near Mackinac Island, MI. The duration of the safety zone is intended to protect personnel, vessels, and the marine environment in these navigable waters during the fireworks display. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP Sault Sainte Marie or his 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. 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).

This regulatory action determination is based on the characteristics of the safety zone. Vessel traffic will be able to safely transit around this safety zone which would impact a small designated area of Lake Huron near Mackinac Island for approximately 3 hours. Moreover, under certain conditions vessels may still transit through the safety zone when permitted by the COTP Sault Sainte Marie or his designated representative.

B. Impact on Small Entities

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

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

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please 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 approximately 3 hours that will prohibit entry within a 750-foot radius of a fireworks display in Lake Huron near Mackinac Island, MI. It is categorically excluded from further review under paragraph L[60(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—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 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. 00170.1, Revision No. 01.2.

■ 2. Add § 165.T09–0516 to read as follows:

§ 165.T09–0516 Safety Zone; Mackinac Island 4th of July Celebration Fireworks, Lake Huron, Mackinac Island, MI.

(a) *Location.* The following area is a safety zone: All navigable water within 750 feet of the fireworks launching location in position 45°50′30″ N, 84°36′30″ W, (NAD 83).

(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 Sault Sainte Marie (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into, transiting, or anchoring within the

safety zone described in paragraph (a) of this section is prohibited unless authorized by the COTP Sault Sainte Marie or his designated representative.

(2) Before a vessel operator may enter or operate within the safety zone, they must obtain permission from the COTP Sault Sainte Marie or his designated representative via VHF Channel 16 or telephone at (906) 635–3233. Vessel operators given permission to enter or operate in the safety zone must comply with all orders given to them by the COTP Sault Sainte Marie or his designated representative.

(d) *Enforcement period.* The safety zone described in paragraph (a) of this section will be enforced from 9 p.m. through 12:01 a.m. on July 4, 2022.

Dated: June 22, 2022.

A.R. Jones,

Captain, U.S. Coast Guard, Captain of the Port Sault Sainte Marie.

[FR Doc. 2022–13678 Filed 6–27–22; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2022–0113; FRL–9656–02–R1]

Air Plan Approval; State Implementation Plan Revisions Required by the 2008 and 2015 Ozone Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving State Implementation Plan (SIP) revisions submitted by the State of Connecticut for purposes of implementing the 2008 and 2015 ozone National Ambient Air Quality Standards (NAAQS). The SIP revisions consist of a demonstration that Connecticut meets the requirements of reasonably available control technology (RACT) for the two precursors for ground-level ozone, oxides of nitrogen (NO_X) and volatile organic compounds (VOCs), set forth by the Clean Air Act (CAA, or the Act) with respect to the 2008 and 2015 ozone standards. We are also approving a Consent Order that establishes NO_X RACT requirements for four facilities in the state. Additionally, we are approving Connecticut's certification that it meets the nonattainment new source review (NNSR) requirements of the CAA for purposes of the 2008 and 2015 ozone standards. This action is being taken in accordance with the Clean Air Act.

DATES: This rule is effective on July 28, 2022.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R01–OAR–2022–0113. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available at *https://www.regulations.gov* or at the U.S. Environmental Protection Agency, EPA Region 1 Regional Office, Air and Radiation Division, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays and facility closures due to COVID–19.

FOR FURTHER INFORMATION CONTACT: Bob McConnell, Air Quality Branch, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square, Suite 100 (mail code 05–2), Boston, MA 02109–3912, telephone number (617) 918–1046, email *mcconnell.robert@epa.gov.*

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

Table of Contents

I. Background and Purpose

On March 25, 2022, (87 FR 17052), EPA published a Notice of Proposed Rulemaking (NPRM) for the State of Connecticut. The NPRM proposed approval of a demonstration that Connecticut meets the requirements of RACT for NO_X and VOCs set forth by the CAA with respect to the 2008 and 2015 ozone standards, and Consent Order #8377 that establishes NO_X RACT requirements for Middletown Power LLC, Montville Power LLC, Connecticut Jet Power LLC, and Devon Power LLC. We note that our March 25, 2022, proposal indicated that these four facilities were owned and operated by NRG Connecticut. However, the Connecticut Department of Energy and Environmental Protection (CT DEEP) provided us with an administrative update to this order to reflect that a new owner, Generation Bridge Acquisition LLC, purchased the assets that are the subject of the order effective as of November 1, 2021. Therefore, on May 5, 2022, CT DEEP submitted an updated order, Consent Order #8377, Modification 1, and we are approving that updated order into the state's SIP. Our March 25, 2022 proposal also proposed to approve negative declarations for a number of source categories for which EPA has established Control Technique Guidelines (CTGs). We note that Connecticut's December 21, 2020, submittal included a negative declaration for EPA's 2016 Oil and Gas CTG, which we approved separately on March 30, 2022 (see 87 FR 18274). Additionally, our NPRM proposed approval of a certification that Connecticut meets the NNSR requirements of the Act for purposes of the 2008 and 2015 ozone standards. The formal SIP revisions were submitted by Connecticut on December 21, 2020. The specific requirements of these SIP revisions and the rationale for EPA's proposed action are explained in the NPRM and will not be restated here. No public comments were received on the NPRM.

II. Final Action

EPA is approving Connecticut's certification that it meets the requirements of RACT for NO_X and VOCs set forth by the CAA with respect to the 2008 and 2015 ozone standards, Consent Order #8377, Modification 1, that establishes NO_X RACT requirements for Middleton Power LLC, Montville Power LLC, Connecticut Jet Power LLC, and Devon Power LLC, and a certification that Connecticut meets the NNSR requirements of the Act for purposes of the 2008 and 2015 ozone standards, as revisions to the Connecticut SIP.

III. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of State of Connecticut, Department of Energy and Environmental Protection, Consent Order #8377, Modification 1, issued to Middletown Power LLC, Montville Power LLC, Connecticut Jet Power LLC, and Devon Power LLC, May 3, 2022. The order establishes NO_X RACT requirements for these facilities for purposes of complying with Phase 2 of the Regulations of Connecticut State

Agencies 22a–174–22e, Control of nitrogen oxide emissions from fuel burning equipment at major stationary sources of nitrogen oxides. The EPA has made, and will continue to make, these documents generally available through *https://www.regulations.gov* and at the EPA Region 1 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 29, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: June 18, 2022.

David Cash,

Regional Administrator, EPA Region 1.

Part 52 of chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart H—Connecticut

■ 2. Section 52.370 is amended by adding paragraph (c)(128) to read as follows:

§ 52.370 Identification of plan.

* * * * *

(c) * * *

(128) Revisions to the State Implementation Plan submitted by the Connecticut Department of Environmental Protection on December 20, 2021 and amended on May 3, 2022.

(i) *Incorporation by reference.* (A) State of Connecticut, Department of Energy and Environmental Protection, Consent Order # 8377, Modification 1, issued to Middletown Power LLC, Montville Power LLC, Connecticut Jet Power LLC, and Devon Power LLC, May 3, 2022.

(B) [Reserved]

(ii) [Reserved]

■ 3. Section 52.375 is amended by adding paragraph (i) to read as follows:

§ 52.375 Certification of no sources.

* * * * *

(i) In its December 21, 2020, submittal to EPA pertaining to reasonably available control technology requirements as a serious area for the 2008 ozone standard and for the 2015 ozone standard as a state containing a moderate nonattainment area and a marginal nonattainment area that is part of the Ozone Transport Region, the State of Connecticut certified to the satisfaction of EPA that no sources located in the State are covered by the following Control Technique Guidelines:

(1) Automobile and Light-Duty Truck Assembly Coatings.

(2) Control of VOC Emissions from Large Petroleum Dry Cleaners.

(3) Fiberglass Boat Manufacturing Materials.

(4) Control of VOC Equipment Leaks from Natural Gas/Gasoline Processing Plants.

(5) Control of Refinery Vacuum Producing Systems, Wastewater Separators, and Process Unit Turnarounds.

(6) Control of Volatile Organic Compound Leaks from Petroleum Refinery Equipment.

(7) Flatwood Paneling Coatings.

(8) The Oil and Natural Gas Industry.

■ 4. Section 52.377 is amended by adding paragraphs (u) and (v) to read as follows:

§ 52.377 Control strategy: Ozone.

* * * * *

(u) *Approval*—Revisions to the Connecticut State Implementation Plan (SIP) submitted on December 21, 2020. The SIP revisions satisfy the requirement to implement reasonably available control technology (RACT) for sources of volatile organic compounds (VOC) and oxides of nitrogen (NO_X) as a serious nonattainment area for purposes of the 2008 ozone standard, and also approves RACT for Connecticut for the 2015 ozone standard as a state containing a moderate nonattainment area and a marginal area that is located within the Ozone Transport Region.

(v) *Approval*—Submittal from the Connecticut Department of Energy and Environmental Protection dated December 21, 2020, to address the nonattainment new source review (NNSR) requirements as a serious nonattainment area for the 2008 8-hour ozone standard for the Greater Connecticut and the New York-N. New Jersey-Long Island, NY-NJ-CT ozone nonattainment areas, and also approves NNSR for Connecticut for the 2015 ozone standard as a state containing a moderate and a marginal nonattainment area and being located within the Ozone Transport Region as it meets the requirements for both the state's marginal and moderate classifications.

[FR Doc. 2022–13539 Filed 6–27–22; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[MD Docket Nos. 21–190 and 22–223; FCC 22–39; FR ID 91796]

Assessment and Collection of Regulatory Fees for Fiscal Year 2022

AGENCY: Federal Communications Commission.

ACTION: Final action.

SUMMARY: In this document, the Federal Communications Commission (Commission) establishes a fee methodology for calculating small satellite fees.

DATES: This final action is effective July 28, 2022. Pursuant to section 9(d) of the Communications Act, the methodology for calculating small satellite fees requires notification to Congress at least 90 days before it becomes effective. Notification to Congress was provided on June 3, 2022, and therefore the effective date for the small satellite methodology is September 1, 2022.

FOR FURTHER INFORMATION CONTACT: Roland Helvajian, Office of Managing Director at (202) 418–0444.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, FCC 22–39, MD Docket Nos. 21–190 and 22–223, adopted on June 1, 2022, and released on June 2, 2022. The full text of this document is available for public inspection by downloading the text from the Commission's website at *https://docs.fcc.gov/public/attachments/FCC-22-39A1.pdf.*

I. Procedural Matters

A. Final Regulatory Flexibility Analysis

1. As required by the Regulatory Flexibility Act of 1980 (RFA), the Commission has prepared a Final Regulatory Flexibility Analysis (FRFA) relating to the *Report and Order.* The FRFA is located at the end of this document.

B. Final Paperwork Reduction Act of 1995 Analysis

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

C. Congressional Review Act

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

II. Introduction

4. In this document, we adopt a fee methodology for calculating small satellite fees.

A. Space Station Regulatory Fees

5. For regulatory fee purposes, space stations are divided into two main categories: (1) geostationary orbit (GSO) space stations and (2) NGSO space stations. With respect to NGSO space stations, consistent with our full time equivalent (FTE) allocation time and the distinct benefits received by small satellite NGSO fee payors, for FY 2022, we adopt a methodology for calculating the regulatory fee for small satellites and small spacecraft (for purposes of this proceeding, we refer to them together as ''small satellites'') based on 1/20th (5%) of the average of the non-small satellite NGSO space station regulatory fee rates from the current fiscal year on a per license basis. To implement this methodology for FY 2022, in the notice of proposed rulemaking (NPRM) published elsewhere in this issue of the **Federal Register** (*FY 2022 NPRM*; FR Doc. 2022–13231), we seek comment on the proposed regulatory fee rates for the subcategories of NGSO—small satellite, NGSO—less complex space stations, and NGSO—other space stations for FY 2022. We also address certain regulatory fee proposals in the record regarding spacecraft involved in on-orbit servicing and rendezvous and proximity operations. We tentatively conclude that the addition of a new regulatory fee category for spacecraft conducting these types of operations would be premature, but seek further comment on this topic, including as it relates to spacecraft that may be conducting on-orbit servicing operations near the GSO arc.

1. Methodology for Calculating Regulatory Fees for Small Satellites and Related Issues

6. Although the Commission adopted the small satellite regulatory fee category in 2019, we are just beginning to implement a fee methodology for satellites and systems licensed as ''small satellites'' because they have just only started to become operational. This fiscal year, we will assess fees against this category of regulatees for the first time given that, as of October 2021, there were five licenses for operational space stations that are in this small satellite regulatory fee category. For the reasons discussed below, our expectation and predictive judgment is that our FTEs will spend approximately twenty times more time on regulating one non-small satellite NGSO system on average compared to the time spent regulating one small satellite license. Thus, in the *FY 2022 NPRM,* we propose a small satellite fee on a per-license basis of $12,145.

7. This proposed fee is based on the methodology we adopt herein by calculating 1/20th (5%) of the average regulatory fee rate for a non-small NGSO system in FY 2022, which we calculated to be $242,878 (the average of the ''less complex'' NGSO space station fee of $142,865 and the ''other'' NGSO space station fee of $342,890, which would be

the fee rates before the small satellite fees are calculated into the total NGSO space station fee category). Then we calculate the actual fee rate for non-small NGSO systems (*i.e.,* NGSO—less complex space stations and NGSO—other space stations) after subtracting the total fee amount that would be allocated to operational small satellites from the total NGSO space station revenues.

8. In 2019, in the *Small Satellite Report and Order,* 85 FR 43711 (July 20, 2020), the Commission adopted a new, optional licensing process for small satellites and spacecraft. In that Report and Order, the Commission also adopted a small satellite regulatory fee category for licensed and operational space stations authorized under the process adopted in that proceeding. The Commission found that these actions would enable such applicants to choose a streamlined licensing procedure resulting in an easier application process, a lower application fee and a shorter timeline for review than currently exists for applicants. Satellites licensed through the streamlined process have characteristics that distinguish them from traditional NGSO satellite space stations, such as having a lower mass, shorter duration missions, more limited spectrum needs, and detailed certifications that must be submitted by the applicant.

9. In the *FY 2018 NPRM,* 83 FR 27846 (June 14, 2018), the Commission proposed a regulatory fee for small satellites that would be 1/20th of the fee applicable to NGSO systems. The Commission observed that this is a new industry sector typically involving relatively low-cost systems, as compared with traditional satellite systems, and a high regulatory fee could limit the commercial applications of small satellites. The Commission also stated that the small satellite rules are designed to lower the regulatory burden involved in licensing small satellites and reduce application processing times. As a result, the Commission expected that small satellite authorizations would take fewer Commission resources to process than traditional NGSO satellite systems. In anticipation of including small satellites in the FY 2022 regulatory fee schedule, in the notice of proposed rulemaking published at 86 FR 52429 (Sept. 21, 2021) (*FY 2021 NPRM*), we sought comment on the methodology for calculating the regulatory fee for this small satellite NGSO regulatory fee category.

10. We first consider the integration of the small satellite NGSO fee category into the NGSO space stations fee category. In the *FY 2021 NPRM,* we sought comment on how we should integrate the small satellite fee category into the overall space stations category. Eutelsat and Intuitive Machines comment that a small satellite fee category should be a third NGSO space stations fee category, in addition to ''less complex'' and ''other.'' In comments responsive to the *FY 2021 NPRM,* Amazon Web Services, Inc. and Planet Labs Inc. also favored integration of the small satellite fee category within the NGSO space stations fee category. We agree with commenters that support integration of the small satellite fee category into the NGSO space stations fee category as a third fee category. This approach recognizes that small satellites encompassed by the streamlined licensing process are, in fact, NGSO space stations. As a result, the small satellite fee category will be the third NGSO space stations fee category, in addition to ''less complex'' and ''other.''

11. We next consider how to calculate the small satellite regulatory fee within the NGSO space stations fee category. In the *FY 2021 NPRM,* we proposed two different ways to assess the small satellite regulatory fee. We first sought comment on setting a fee for small satellites that would not be dependent on the number of small satellites operating in a given regulatory period. We noted that a set fee would provide more certainty for regulatees given the shorter missions lasting no longer than six years for small satellites and the likely higher fluctuation in number of small satellites that are licensed and operational each year compared to NGSO space stations that are licensed for a 15-year term. More specifically, we proposed a fee for small satellites that is 1/20th of the ''other'' NGSO space station fee category, either calculated using the ''other'' NGSO space stations fees for given year or using the FY 2021 fee and then reassessing accordingly each year, since the FTE activities for given small satellite space stations would be approximately 1/20th of the FTE activities for typical ''other'' NGSO space stations.

12. Commenters responded to this proposal with varying suggestions for calculating the regulatory fee for small satellites. Eutelsat proposes that we estimate aggregate small satellite regulatory costs annually by imposing a regulatory fee that is 1/20th of the average NGSO space stations fee, which would be calculated by dividing total expected NGSO space stations fee revenues by the number of traditional NGSO systems or ''payment units.'' Eutelsat proposes that we then adjust downward the fees for ''other'' and ''less complex'' NGSO space stations. Eutelsat submits that this methodology mitigates the potential for unexpectedly large and unsupportable fee amounts resulting from significant changes in workload or the number of small satellites from year to year. Eutelsat suggests that this small satellite regulatory fee of 1/20th of the average NGSO space stations fee would be a ''middle ground'' and provide an opportunity to gain more experience in regulating small satellites and understanding the benefits they receive. Eutelsat notes that the benefits received by small satellite licensees from Commission regulatory activities are limited due to compatibility requirements with existing operations and the limited license term compared to traditional NGSO space stations. Eutelsat also emphasizes the importance of stability in regulatory fee amounts since small satellite systems generally have more limited potential to generate commercial revenues or are used to further scientific/experimental objectives.

13. Alternatively, Astro Digital proposes a fixed regulatory fee for small satellites that is 1/20th of the FY 2021 fee for ''other'' NGSO space stations and will vary minimally from year to year. Astro Digital posits that a fixed fee helps to ensure predictability for operators. Astro Digital believes that such a fee reflects the appropriate regulatory burden to the Commission and the benefits received by small satellite operators. Astro Digital also submits that this fee further accounts for reduced regulatory burden due to the operators typically being involved in likely less contentious licensing proceedings.

14. As another alternative, Intuitive Machines proposes a fee that is 1/20th of the ''less complex'' NGSO space stations regulatory fee to more closely approximate the benefits and burdens associated with regulating small satellites. Intuitive Machines suggests this fee in consideration of the Commission's estimate that FTE activities for small satellites would be approximately 1/20th of the FTE activities for the category of ''other'' NGSO space stations, which is similar to the Commission's findings in the *FY 2018 Report and Order,* 83 FR 47079 (Sept. 18, 2018). Intuitive Machines argues that when the Commission proposed a fee in the *FY 2018 Report and Order* that was 1/20th of the then NGSO space stations regulatory fee of $135,350, which was later lowered to $122,775, the resulting regulatory fee calculated to approximately $6,139—virtually identical to $6,135 or 1/20th of the FY 2021 ''less complex'' NGSO

space stations fee category today. Intuitive Machines claims that this fee assessment is not only consistent with the Commission's prior proposal to account for FTE activities but also accounts for the reduced benefits received by small spacecraft operators.

15. In the *FY 2021 NPRM,* we also sought comment on whether to allocate a percentage of the allocation for space station fees for small satellites, which would cause the amount to fluctuate each year depending on the number of payors in the small satellite category. We noted that there would likely be few small satellite operators paying fees initially and that the percentage could be reassessed as the number of operational small satellites and FTE activities involving those small satellites increases. We also sought comment on the earlier proposals of AWS and Planet Labs to allocate 5% of the total NGSO space station fee requirement to the small satellite fee category. The remaining 95% would be divided between the ''less complex'' and ''other'' NGSO space stations. However, we expressed concern about redistributing solely a percentage of the ''less complex'' NGSO space stations fee to systems authorized under the streamlined small satellite process, given that there are important differences between small satellites and ''less complex'' and ''other'' NGSO space station systems that we believe necessitate different regulatory fees.

16. Based on the record, and the fact that small satellites are NGSO space stations, we adopt a methodology for calculating the regulatory fee rate for small satellites based on 1/20th (5%) of the average of the ''less complex'' NGSO space station regulatory fee rate and the ''other'' NGSO space station fee rate for the current fiscal year. In determining the average of the NGSO space station regulatory fee rate for the current year, we will add together the fee rates of one ''less complex'' and one ''other'' NGSO space station units, before taking into account small satellite fees in the NGSO fee category, and divide that value by two. This averaging methodology accommodates fluctuations in the number of NGSO space stations fee payors and will result in a relatively and appropriately low regulatory fee for small satellites. We also find that adopting this averaging methodology rather than taking a percentage of either the ''less complex'' or ''other'' NGSO space station fee rate provides a middle ground and an opportunity to gain more experience in regulating small satellites, while also recognizing that small satellites are part of a separate fee category and not within either the ''less complex'' or ''other'' NGSO space stations fee categories.

17. We agree with commenters responding to the *FY 2021 NPRM* that a fair, administrable, and sustainable approach for assessing regulatory fees for small satellites is through calculating a fee that is not solely dependent on the number of small satellites operating in a given regulatory period. In addition, we find that a small satellite fee based on 1/20th (5%) of the average of the NGSO space stations regulatory fee rate from the current fiscal year will fairly reflect the anticipated FTE time for regulating small satellites. Our methodology results in a predictable small satellite regulatory fee structure (since the average of the ''less complex'' and ''other'' NGSO space station fees is unlikely to fluctuate significantly each year), takes into account the differences in small satellite licensing processes, accounts for regulatory differences among NGSO space stations, and aims to reduce the risk of non payors by increasing certainty as to the anticipated approximate small satellite regulatory fees.

18. Our methodology also takes into account the amount of work that FTEs are performing and our expectation that our FTEs will spend approximately twenty times more time on regulating one non-small NGSO space station system compared to the time spent for regulating one small satellite license. With each small satellite application, the total FTE work amount in a given year increases. We anticipate that FTEs will spend time regulating small satellites by performing International Telecommunication Union (ITU) coordination; conducting outreach to other administrations; working on rulemakings, adjudications, and licensing; handling various filings submitted by small satellite operators; handling enforcement issues; and accounting for the potentially variable number of earth stations with which small satellites may communicate, including updating ITU materials when operators add earth stations to their networks after initial licensing. Small satellite regulatees, in turn, benefit from this regulatory work. This fee methodology simultaneously accounts for the characteristics of small satellites and the relatively few work hours anticipated to be spent by International Bureau FTEs in regulating them compared to FTE time spent on non-small satellite NGSO space stations, since small satellites have streamlined processing, often limited operational capabilities, spectrum compatibility requirements, and can only be licensed for a period of up to six years.

19. Our regulatory fee methodology for small satellites also should reduce artificial incentives for structuring license applications primarily for the purpose of avoiding NGSO regulatory fees. Given the unique regulatory framework and optional application process, as well as the fact that most regulatory activities benefit all NGSO space stations in some proportion and our FTE activities are not tracked based on each NGSO subcategory, calculating the small satellite fee rate on a per license basis and in relation to FTE activities involving a non-small NGSO space station on average will ensure that NGSO space stations fee payors are assessed fair and reasonable shares of the total NGSO space stations regulatory fees.

20. As the small satellite fee is calculated, the fees generated from this small satellite fee category will be deducted from the fee amount to be collected from the total NGSO space stations fees, and then the remainder of the NGSO space stations fees will be allocated on an 80/20 basis between ''other'' and ''less complex'' NSGO space stations respectively. This approach is consistent with our statutory obligation to apportion cost of regulating NGSO space stations in a fair and administrable manner among the NGSO space station fee payors. In adopting the small satellite fee category, the Commission recognized that small satellites are NGSO space stations. Taking out the small satellite fees from the total NGSO fees, rather than from one of the NGSO space station subcategories, recognizes that any small satellite fee contribution to the total fees collected from NGSO space stations should reduce the fees collected from both the ''less complex'' and ''other'' NGSO space stations in the same manner to keep the cost apportionment between those subcategories at a fair and reasonable level. As we indicated in the *FY 2021 Report and Order,* 86 FR 52742 (Sept. 22, 2021), FY 2022 will be the first year we assess regulatory fees for small satellites, and we anticipate that we will continue to review regulatory fees for small satellites on an ongoing basis as we gain more experience with these licensees.

21. *Assessment of Fees on a Per-License Basis.* In the *FY 2021 NPRM,* we sought comment on whether we should assess regulatory fees per system or differently than other NGSO fee categories, given that a single entity may have multiple licenses for the same system, in accordance with the structure of the small satellite process. We sought to account for the fact that one system may have multiple associated small

satellite licenses. In response, both Eutelsat and Intuitive Machines propose that we should assess regulatory fees for small satellites per small satellite system rather than per small satellite license. Intuitive Machines contends that licensing on a per-system basis would provide small spacecraft operators greater flexibility in licensing missions and would benefit non-Earth orbiting systems that may be deployed incrementally over timeframes that may not be consistent with the orbital lifetime contemplated for small spacecraft. Eutelsat favors a per-system basis because small satellite systems may be associated with multiple licenses, therefore having multiple call signs, in part because of the design of the small satellite licensing process. Eutelsat also suggests that adopting fees on a per-system basis would avoid discouraging applicants from applying for multiple licenses because of potential regulatory fees and argues that such a policy would account for the diverse implementation options for small satellite systems.

22. We decline to adopt a per-system fee and instead adopt the small satellite regulatory fee on a per-license basis. We anticipate that adopting the fee on a per-license basis will accurately reflect the increased oversight and regulation required by International Bureau FTEs for these systems, including ongoing regulatory activities, when an operator has multiple small satellite licenses. We have experienced firsthand a correlation between the time spent by FTEs in regulating small satellites and the number of licenses for a small satellite system when issuing multiple licenses to a small satellite operator. We also anticipate that a per-license fee basis will be more efficient and administrable because it avoids potential complications and additional FTE time spent in determining whether various sets of small satellites are part of the same ''system.'' Applying this fee on a per-license basis also is consistent with the Commission's statutory obligation to recover its costs while taking into account differences between the small satellite regulatory framework compared to other space stations, as discussed in more detail below, and acknowledges that there may be some advantages and additional benefits for small satellite operators to have more than one license given the shorter license term. Finally, we note that each small satellite license is assigned its own call sign in the application process, and so a small satellite call sign is effectively a proxy for license file number. As a result, in order to simplify our invoicing processing, we plan to invoice small satellite regulatory fees per call sign.

23. We anticipate that adopting a fee for small satellites on a per-license basis rather than a per-system basis used for traditional NGSO space stations will account for key differences in the regulation of small satellites. First, when a small satellite operator has multiple licenses, the number of licenses correlates with the amount of work that the Commission must perform. This per-license fee basis will account for the anticipated additional burden in regulating more complicated multi-launch small satellite systems. In contrast, the Commission has observed that when traditional NGSO space stations operators hold multiple licenses for a single NGSO system, the regulatory burden does not increase with the grant of each additional license. Traditional NGSO systems are substantially more complicated to regulate from the outset, which could include processing rounds and related disputes and greater involvement in international coordination, such that additional authorizations create at most a nominal, if any, adjustment to the burden to regulate.

24. Second, we expect that there are greater incentives and benefits of obtaining multiple licenses for the same system for small satellites compared to traditional NGSO space stations. For example, small satellite licenses are short term, lasting up to six years, while other NGSO space station licenses are valid for 15 years. As another example, a single small satellite license can only authorize up to 10 satellites; however, under an NGSO licensing framework, there is no limit on the number of satellites that can be authorized under a single license. The small satellite licensing process is an optional streamlined process, carefully crafted to streamline regulatory work per application. Unlike other NGSO space station constellations, small satellite ''systems'' involving larger numbers of satellites cannot be authorized under a single license. The license term is also relatively short so with each additional small satellite license, operators of small satellite systems receive distinct benefits. For these reasons, we conclude that assessing the regulatory fee on a per-license basis is consistent with section 9 of the Communications Act and such assessments can be expected to reflect more accurately the FTE time spent on regulating these fee payors and the regulatory benefits provided to them.

25. Our actions here are under section 9(d) of the Communications Act and must be submitted to Congress at least 90 days before they become effective. We direct the Office of the Managing Director to issue the notice immediately upon release of the item.

26. *Non-U.S. Licensed Small Satellite Operators.* We deny the request from RBC Signals to exempt from regulatory fees non-U.S. licensed small satellite operators ''whose only connection with the U.S. market is communicating with U.S. data link/[telemetry, tracking and command] TT&C earth stations.'' RBC Signals argues that the Commission's analysis in the *FY 2020 Report and Order* (85 FR 59864 (Sept. 23, 2020)) supports such an exemption. RBC Signals contends that, given their limited communications capabilities, small satellites typically utilize the same earth stations and low data-rate links for TT&C and data transfer. RBC Signals adds that the data transferred using these links are minimal as compared to gateway/feeder link backhaul for large communications and similar satellites. As a result, RBC Signals believes that small satellites communicating with U.S. earth stations only for data link and TT&C operations meet the factors that the Commission previously found were not present when denying creation of fee exemptions for certain non-U.S. licensed satellite systems: facilitation of safe operation of satellites and avoidance of significant data exchange traffic. RBC Signals contends that the costs of non-U.S. licensed small satellites supported by U.S. data link/TT&C earth stations should be recovered in the regulation of the U.S. earth stations, which also primarily receive the corresponding regulatory benefits. RBC Signals posits that small satellite ''data link/TT&C'' communications involve a narrow range of spectrum bands used for much more limited purposes and that it makes little difference whether a small satellite's supporting data link/TT&C earth station is located within or outside U.S. territory.

27. For the following reasons, we disagree with RBC Signals' proposal that the Commission should exempt non-U.S. licensed small satellite operators whose only connection with the U.S. market is communicating with U.S. data link earth stations. RBC does not provide any meaningful distinction between data link stations and the gateway/feeder link stations previously addressed in the *FY 2020 Report and Order.* In that Report and Order, the Commission found that space station operators benefit from our regulatory actions regardless of the direction of the data flow or whether services are provided ultimately to end users in the United States. The Commission also

found that non-U.S. licensed satellites accessing U.S. gateway/feeder link earth stations and non-U.S. licensed NGSO systems that downlink traffic to U.S. licensed earth stations, solely for immediate transit outside the United States, are involved in significant data exchange traffic in the United States and are not exempt from regulatory fees. With respect to small satellites, we note the Commission's earlier conclusion that services including TT&C and non-domestic data link to, or data link from, earth stations in the United States are meaningfully gaining access to the U.S. market and are subject to regulatory fees. We also note that the Commission has made clear that operators that communicate with TT&C earth stations in the United States will not pay regulatory fees, but only where the relevant earth station license clearly limits the non-U.S. licensed space station's access to TT&C communications. RBC Signals' request to exempt a space station communicating with a data link earth station exceeds that limit that the Commission has previously determined.

III. Final Regulatory Flexibility Analysis

28. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), an Initial Regulatory Flexibility Analysis (IRFA) was included in the *FY 2021 NPRM.* The Commission sought written public comment on these proposals, including comment on the IRFA. This Final Regulatory Flexibility Analysis (FRFA) conforms to the IRFA.

A. Need for, and Objectives of, the Report and Order

29. The Commission is required by Congress to assess regulatory fees each year in an amount that can reasonably be expected to equal the amount of its annual appropriation. Although the Commission adopted the small satellite regulatory fee category in 2019, we are still at the start of implementing a fee methodology for satellites and systems licensed as ''small satellites'' because they have just only started to become operational. This fiscal year, we would apply this category of fees for the first time given that, as of October 2021, there were 5 licenses for operational space stations that fall in this small satellite regulatory fee category. In the Report and Order, we adopt a methodology for calculating the regulatory fee for small satellites and small spacecraft (for purposes of this proceeding, we refer to them together as ''small satellites'') based on 1/20th (5%) of the average of the non-small satellite non-geostationary orbit (NGSO) space station regulatory fee rates from the current fiscal year. We adopt this fee on a per-license basis. This methodology will recognize the more limited regulatory work associated with small satellite licenses. It also results in a relatively low regulatory fee for small satellites. FY 2022 will be the first year we assess regulatory fees for small satellites, so we anticipate that the Commission will review the regulatory fees for small satellites on an ongoing basis as it gains more experience with these licensees and market access grantees. In the Report and Order, we also deny an exemption requested from regulatory fee obligations for non-US licensed space stations.

B. Summary of the Significant Issues Raised by the Public Comments in Response to the IRFA

30. None.

C. Response to Comments by the Chief Counsel for Advocacy of the Small Business Administration

31. No comments were filed by the Chief Counsel for Advocacy of the Small Business Administration.

D. Description and Estimate of the Number of Small Entities to Which the Rules Will Apply

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

33. *Small Businesses, Small Organizations, Small Governmental Jurisdictions. Small Businesses, Small Organizations, Small Governmental Jurisdictions.* Our actions, over time, may affect small entities that are not easily categorized at present. We therefore describe here, at the outset, three broad groups of small entities that could be directly affected herein. First, while there are industry specific size standards for small businesses that are used in the regulatory flexibility analysis, according to data from the SBA's Office of Advocacy, in general a small business is an independent business having fewer than 500 employees. These types of small businesses represent 99.9% of all businesses in the United States, which translates to 30.7 million businesses.

34. Next, the type of small entity described as a ''small organization'' is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' The Internal Revenue Service (IRS) uses a revenue benchmark of $50,000 or less to delineate its annual electronic filing requirements for small exempt organizations. Nationwide, for tax year 2018, there were approximately 571,709 small exempt organizations in the U.S. reporting revenues of $50,000 or less according to the registration and tax data for exempt organizations available from the IRS.

35. Finally, the small entity described as a ''small governmental jurisdiction'' is defined generally as ''governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.'' U.S. Census Bureau data from the 2017 Census of Governments indicates that there were 90,075 local governmental jurisdictions consisting of general purpose governments and special purpose governments in the United States. Of this number there were 36,931 general purpose governments (county, municipal and town or township) with populations of less than 50,000 and 12,040 special purpose governments—independent school districts with enrollment populations of less than 511 governmental jurisdictions.''

36. *Wired Telecommunications Carriers.* The U.S. Census Bureau defines this industry as establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired communications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services, wired (cable) audio and video programming distribution, and wired broadband internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry. Wired Telecommunications Carriers are also referred to as wireline carriers or fixed local service providers.

37. The SBA small business size standard for Wired Telecommunications Carriers classifies firms having 1,500 or fewer employees as small. U.S. Census Bureau data for 2017 shows that there were 3,054 firms that operated in this industry for the entire year. Of this number, 2,964 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2021 Universal Service Monitoring Report, as of December 31, 2020, there were 5,183 providers that reported they were engaged in the provision of fixed local services. Of these providers, the Commission estimates that 4,737 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

38. *Local Exchange Carriers (LECs).* Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to local exchange services. Providers of these services include both incumbent and competitive local exchange service providers. Wired Telecommunications Carriers is the closest industry with an SBA small business size standard. Wired Telecommunications Carriers are also referred to as wireline carriers or fixed local service providers. The SBA small business size standard for Wired Telecommunications Carriers classifies firms having 1,500 or fewer employees as small. U.S. Census Bureau data for 2017 shows that there were 3,054 firms that operated in this industry for the entire year. Of this number, 2,964 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2021 Universal Service Monitoring Report, as of December 31, 2020, there were 5,183 providers that reported they were fixed local exchange service providers. Of these providers, the Commission estimates that 4,737 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

39. *Incumbent Local Exchange Carriers (Incumbent LECs).* Neither the Commission nor the SBA have developed a small business size standard specifically for incumbent local exchange carriers. Wired Telecommunications Carriers is the closest industry with an SBA small business size standard. The SBA small business size standard for Wired Telecommunications Carriers classifies firms having 1,500 or fewer employees as small. U.S. Census Bureau data for 2017 shows that there were 3,054 firms in this industry that operated for the entire year. Of this number, 2,964 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2021 Universal Service Monitoring Report, as of December 31, 2020, there were 1,227 providers that reported they were incumbent local exchange service providers. Of these providers, the Commission estimates that 929 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, the Commission estimates that the majority of incumbent local exchange carriers can be considered small entities.

40. *Competitive Local Exchange Carriers (LECs).* Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to local exchange services. Providers of these services include several types of competitive local exchange service providers. Wired Telecommunications Carriers is the closest industry with an SBA small business size standard. The SBA small business size standard for Wired Telecommunications Carriers classifies firms having 1,500 or fewer employees as small. U.S. Census Bureau data for 2017 shows that there were 3,054 firms that operated in this industry for the entire year. Of this number, 2,964 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2021 Universal Service Monitoring Report, as of December 31, 2020, there were 3,956 providers that reported they were competitive local exchange service providers. Of these providers, the Commission estimates that 3,808 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

41. *Interexchange Carriers (IXCs).* Neither the Commission nor the SBA have developed a small business size standard specifically for Interexchange Carriers. Wired Telecommunications Carriers is the closest industry with an SBA small business size standard. The SBA small business size standard for Wired Telecommunications Carriers classifies firms having 1,500 or fewer employees as small. U.S. Census Bureau data for 2017 shows that there were 3,054 firms that operated in this industry for the entire year. Of this number, 2,964 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2021 Universal Service Monitoring Report, as of December 31, 2020, there were 151 providers that reported they were engaged in the provision of interexchange services. Of these providers, the Commission estimates that 131 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, the Commission estimates that the majority of providers in this industry can be considered small entities.

42. *Prepaid Calling Card Providers.* Neither the Commission nor the SBA has developed a small business size standard specifically for prepaid calling card providers. Telecommunications Resellers is the closest industry with an SBA small business size standard. The Telecommunications Resellers industry comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and reselling wired and wireless telecommunications services (except satellite) to businesses and households. Establishments in this industry resell telecommunications; they do not operate transmission facilities and infrastructure. Mobile virtual network operators (MVNOs) are included in this industry. The SBA small business size standard for Telecommunications Resellers classifies a business as small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2017 shows that 1,386 firms in this industry provided resale services for the entire year. Of that number, 1,375 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2021 Universal Service Monitoring Report, as of December 31, 2020, there were 58 providers that reported they were engaged in the provision of payphone services. Of these providers, the Commission estimates that 57 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

43. *Local Resellers.* Neither the Commission nor the SBA have developed a small business size standard specifically for Local Resellers. Telecommunications Resellers is the closest industry with an SBA small business size standard. The Telecommunications Resellers industry comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and reselling wired and wireless telecommunications services (except satellite) to businesses and households. Establishments in this industry resell telecommunications; they do not

operate transmission facilities and infrastructure. Mobile virtual network operators (MVNOs) are included in this industry. The SBA small business size standard for Telecommunications Resellers classifies a business as small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2017 shows that 1,386 firms in this industry provided resale services for the entire year. Of that number, 1,375 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2021 Universal Service Monitoring Report, as of December 31, 2020, there were 293 providers that reported they were engaged in the provision of local resale services. Of these providers, the Commission estimates that 289 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

44. *Toll Resellers.* Neither the Commission nor the SBA have developed a small business size standard specifically for Toll Resellers. Telecommunications Resellers is the closest industry with an SBA small business size standard. The Telecommunications Resellers industry comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and reselling wired and wireless telecommunications services (except satellite) to businesses and households. Establishments in this industry resell telecommunications; they do not operate transmission facilities and infrastructure. Mobile virtual network operators (MVNOs) are included in this industry. The SBA small business size standard for Telecommunications Resellers classifies a business as small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2017 shows that 1,386 firms in this industry provided resale services for the entire year. Of that number, 1,375 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2021 Universal Service Monitoring Report, as of December 31, 2020, there were 518 providers that reported they were engaged in the provision of toll services. Of these providers, the Commission estimates that 495 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

45. *Other Toll Carriers.* Neither the Commission nor the SBA has developed a definition for small businesses specifically applicable to Other Toll Carriers. This category includes toll carriers that do not fall within the categories of interexchange carriers, operator service providers, prepaid calling card providers, satellite service carriers, or toll resellers. Wired Telecommunications Carriers is the closest industry with an SBA small business size standard. The SBA small business size standard for Wired Telecommunications Carriers classifies firms having 1,500 or fewer employees as small. U.S. Census Bureau data for 2017 shows that there were 3,054 firms in this industry that operated for the entire year. Of this number, 2,964 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2021 Universal Service Monitoring Report, as of December 31, 2020, there were 115 providers that reported they were engaged in the provision of other toll services. Of these providers, the Commission estimates that 113 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

46. *Wireless Telecommunications Carriers (except Satellite).* This industry comprises establishments engaged in operating and maintaining switching and transmission facilities to provide communications via the airwaves. Establishments in this industry have spectrum licenses and provide services using that spectrum, such as cellular services, paging services, wireless internet access, and wireless video services. The SBA size standard for this industry classifies a business as small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2017 shows that there were 2,893 firms in this industry that operated for the entire year. Of that number, 2,837 firms employed fewer than 250 employees. Additionally, based on Commission data in the 2021 Universal Service Monitoring Report, as of December 31, 2020, there were 797 providers that reported they were engaged in the provision of wireless services. Of these providers, the Commission estimates that 715 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

47. *Television Broadcasting.* This industry is comprised of ''establishments primarily engaged in broadcasting images together with sound.'' These establishments operate television broadcast studios and facilities for the programming and transmission of programs to the public. These establishments also produce or transmit visual programming to affiliated broadcast television stations, which in turn broadcast the programs to the public on a predetermined schedule. Programming may originate in their own studio, from an affiliated network, or from external sources. The SBA small business size standard for this industry classifies businesses having $41.5 million or less in annual receipts as small. The 2017 U.S. Census Bureau data indicates that 744 firms in this industry operated for the entire year. Of that number, 657 firms had revenue of less than $25,000,000. Based on this data we estimate that the majority of television broadcasters are small entities under the SBA small business size standard.

48. The Commission estimates that as of September 2021, there were 1,374 licensed commercial television stations, 384 licensed noncommercial educational (NCE) television stations, 2,276 low power television stations, including Class A stations (LPTV) and 3,106 TV translator stations. The Commission however does not compile, and otherwise does not have access to financial information for these television broadcast stations that would permit it to determine how many of these stations qualify as small entities under the SBA small business size standard. Nevertheless, given the SBA's large annual receipts threshold for this industry and the nature of television station licensees, we presume that all of these entities qualify as small entities under the above SBA small business size standard.

49. *Radio Stations.* This industry is comprised of ''establishments primarily engaged in broadcasting aural programs by radio to the public.'' Programming may originate in their own studio, from an affiliated network, or from external sources. The SBA small business size standard for this industry classifies firms having $41.5 million or less in annual receipts as small. U.S. Census Bureau data for 2017 shows that 2,963 firms operated in this industry during that year. Of this number, 1,879 firms operated with revenue of less than $25 million per year. Based on this data and the SBA's small business size standard, we estimate a majority of such entities are small entities.

50. The Commission estimates that as of September 2021, there were 4,519 licensed commercial AM radio stations, 6,682 licensed commercial FM radio stations and 4,211 licensed noncommercial (NCE) FM radio stations. The Commission however does not compile, and otherwise does not have access to financial information for

these radio stations that would permit it to determine how many of these stations qualify as small entities under the SBA small business size standard. Nevertheless, given the SBA's large annual receipts threshold for this industry and the nature of radio station licensees, we presume that all of these entities qualify as small entities under the above SBA small business size standard.

51. *Cable Companies and Systems (Rate Regulation).* The Commission has developed its own small business size standard for the purpose of cable rate regulation. Under the Commission's rules, a ''small cable company'' is one serving 400,000 or fewer subscribers nationwide. Based on available data, as of December 2020, there were approximately 45,308,192 basic cable video subscribers in the top Cable multiple system operators (MSOs) in the United States. Only five cable operators serving cable video subscribers in the top Cable MSOs had more than 400,000 subscribers. Accordingly, the Commission estimates that the majority of cable operators are small.

52. *Cable System Operators (Telecom Act Standard).* The Communications Act of 1934, as amended, contains a size standard for small cable system operators, which classifies ''a cable operator that, directly or through an affiliate, serves in the aggregate fewer than one percent of all subscribers in the United States and is not affiliated with any entity or entities whose gross annual revenues in the aggregate exceed $250,000,000,'' as small. As of December 2020, there were approximately 45,308,192 basic cable video subscribers in the top Cable MSOs in the United States. Accordingly, an operator serving fewer than 453,082 subscribers shall be deemed a small operator if its annual revenues, when combined with the total annual revenues of all its affiliates, do not exceed $250 million in the aggregate. Based on available data, all but five of the cable operators in the Top Cable MSOs have less than 453,082 subscribers and can be considered small entities under this size standard. We note however, that the Commission neither requests nor collects information on whether cable system operators are affiliated with entities whose gross annual revenues exceed $250 million. Therefore, we are unable at this time to estimate with greater precision the number of cable system operators that would qualify as small cable operators under the definition in the Communications Act.

53. *Direct Broadcast Satellite (DBS) Service.* DBS service is a nationally distributed subscription service that delivers video and audio programming via satellite to a small parabolic ''dish'' antenna at the subscriber's location. DBS is included in the Wired Telecommunications Carriers industry which comprises establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired telecommunications networks. Transmission facilities may be based on a single technology or combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services, wired (cable) audio and video programming distribution; and wired broadband internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry.

54. The SBA small business size standard for Wired Telecommunications Carriers classifies firms having 1,500 or fewer employees as small. U.S. Census Bureau data for 2017 shows that 3,054 firms operated in this industry for the entire year. Of this number, 2,964 firms operated with fewer than 250 employees. Based on this data, the majority of firms in this industry can be considered small under the SBA small business size standard. According to Commission data however, only two entities provide DBS service—DIRECTV (owned by AT&T) and DISH Network, which require a great deal of capital for operation. DIRECTV and DISH Network both exceed the SBA size standard for classification as a small business. Therefore, we must conclude based on internally developed Commission data, in general DBS service is provided only by large firms.

55. *Satellite Telecommunications.* This industry comprises firms ''primarily engaged in providing telecommunications services to other establishments in the telecommunications and broadcasting industries by forwarding and receiving communications signals via a system of satellites or reselling satellite telecommunications.'' Satellite telecommunications service providers include satellite and earth station operators. The SBA small business size standard for this industry classifies a business with $35 million or less in annual receipts as small. U.S. Census Bureau data for 2017 shows that 275 firms in this industry operated for the entire year. Of this number, 242 firms had revenue of less than $25 million. Additionally, based on Commission data in the 2021 Universal Service Monitoring Report, as of December 31, 2020, there were 71 providers that reported they were engaged in the provision of satellite telecommunications services. Of these providers, the Commission estimates that approximately 48 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, a little more than of these providers can be considered small entities.

56. *All Other Telecommunications.* This industry is comprised of establishments primarily engaged in providing specialized telecommunications services, such as satellite tracking, communications telemetry, and radar station operation. This industry also includes establishments primarily engaged in providing satellite terminal stations and associated facilities connected with one or more terrestrial systems and capable of transmitting telecommunications to, and receiving telecommunications from, satellite systems. Providers of internet services (*e.g.,* dial-up ISPs) or voice over internet protocol (VoIP) services, via client-supplied telecommunications connections are also included in this industry. The SBA small business size standard for this industry classifies firms with annual receipts of $35 million or less as small. U.S. Census Bureau data for 2017 shows that there were 1,079 firms in this industry that operated for the entire year. Of those firms, 1,039 had revenue of less than $25 million. Based on this data, the Commission estimates that the majority of ''All Other Telecommunications'' firms can be considered small.

57. *RespOrgs.* Responsible Organizations, or RespOrgs (also referred to as Toll-Free Number (TFN) providers), are entities chosen by toll free subscribers to manage and administer the appropriate records in the toll-free Service Management System for the toll-free subscriber. Based on information on the website of SOMOS, the entity that maintains a registry of Toll-Free Number providers (SMS/800 TFN Registry) for the more than 42 million Toll-Free numbers in North America, and the TSS Registry, a centralized registry for the use of Toll-Free Numbers in text messaging and multimedia services, there were approximately 446 registered RespOrgs/Toll-Free Number providers in July 2021. RespOrgs are often wireline carriers, however they can include non-carrier entities. Accordingly, the

description below for RespOrgs include both Carrier RespOrgs and Non-Carrier RespOrgs.

58. *Carrier RespOrgs.* Neither the Commission nor the SBA have developed a small business size standard for Carrier RespOrgs. *Wired Telecommunications Carriers,* and *Wireless Telecommunications Carriers (except Satellite)* are the closest industries with an SBA small business size applicable to Carrier RespOrgs.

59. *Wired Telecommunications Carriers* are establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired communications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services, wired (cable) audio and video programming distribution, and wired broadband internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry. The SBA small business size standard for this industry classifies a business as small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2017 shows that there were 3,054 firms that operated for the entire year. Of this number, 2,964 firms operated with fewer than 250 employees. Based on that data, we conclude that the majority of Carrier RespOrgs that operated with wireline-based technology are small.

60. *Wireless Telecommunications Carriers (except Satellite)* engage in operating and maintaining switching and transmission facilities to provide communications via the airwaves. Establishments in this industry have spectrum licenses and provide services using that spectrum, such as cellular services, paging services, wireless internet access, and wireless video services. The SBA small business size standard for this industry classifies a business as small if it has 1,500 or fewer employees. For this industry, U.S. Census Bureau data for 2017 shows that there were 2,893 firms that operated for the entire year. Of this number, 2,837 firms employed fewer than 250 employees. Based on this data, we conclude that the majority of Carrier RespOrgs that operated with wireless-based technology are small.

61. *Non-Carrier RespOrgs.* Neither the Commission, nor the SBA have developed a small business size standard Non-Carrier RespOrgs. *Other Services Related to Advertising* and *Other Management Consulting Services* are the closest industries with an SBA small business size applicable to Non-Carrier RespOrgs.

62. The *Other Services Related to Advertising* industry contains establishments primarily engaged in providing advertising services (except advertising agency services, public relations agency services, media buying agency services, media representative services, display advertising services, direct mail advertising services, advertising material distribution services, and marketing consulting services). The SBA small business size standard for this industry classifies a business as small that has annual receipts of $16.5 million or less. U.S. Census Bureau data for 2017 shows that 5,650 firms operated in this industry for the entire year. Of that number, 3,693 firms operated with revenue of less than $10 million. Based on this data, we conclude that a majority of non-carrier RespOrgs who provide TFN-related management consulting services are small.

63. The *Other Management Consulting Services* industry contains establishments primarily engaged in providing management consulting services (except administrative and general management consulting; human resources consulting; marketing consulting; or process, physical distribution, and logistics consulting). Establishments providing telecommunications or utilities management consulting services are included in this industry. The SBA small business size standard for this industry classifies a business as small if it has annual receipts of $16.5 million or less. U.S. Census Bureau data for 2017 shows that 4,696 firms operated in this industry for the entire year. Of that number, 3,700 firms had revenue of less than $10 million. Based on this data, we conclude that a majority of non-carrier RespOrgs who provide TFN-related management consulting services are small.

E. Description of Projected Reporting, Recordkeeping and Other Compliance Requirements

64. The Report and Order does not adopt any new reporting, recordkeeping, or other compliance requirements.

F. Steps Taken To Minimize Significant Economic Impact on Small Entities and Significant Alternatives Considered

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

66. In the Report and Order, the Commission adopted a methodology for calculating the regulatory fee for small satellites (a type of non-geostationary orbit space station) at a much lower amount than non-geostationary orbit space stations are assessed. This was designed to allow small satellites, which may be licensed by small entities, to operate without the financial burden of the alternative, *i.e.,* paying the regulatory fee for non-geostationary orbit space stations. This new methodology was adopted specifically to minimize the economic burden for these small satellite systems. The Commission considered other options raised by commenters to calculate the regulatory fee for small satellites but ultimately determined, based on the record, that the adopted methodology best recognizes the limited regulatory work associated with small satellite licenses and results in a relatively low regulatory fee for small satellites.

67. Additionally, the Commission has minimized the economic impact on small entities by adopting a de minimis threshold under the section 9(e)(2) exemption in the Communications Act. Under the section 9(e)(2) exemption of the Communications Act, a regulatee is exempt from paying regulatory fees if the sum total of all of its annual regulatory fee liabilities is $1,000 or less for the fiscal year. The threshold applies only to annual regulatory fees, not regulatory fees paid through multi-year filings.

G. Report to Congress

68. The Commission will send a copy of the Report and Order and Notice of Proposed Rulemaking, including this FRFA, in a report to be sent to Congress and the Government Accountability Office pursuant to the Small Business Regulatory Enforcement Fairness Act of

1996. In addition, the Commission will send a copy of the Report and Order and Notice of Proposed Rulemaking, including the FRFA, to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the Report and Order and Notice of Proposed Rulemaking and FRFA (or summaries thereof) will also be published in the **Federal Register**.

IV. Ordering Clauses

69. Accordingly, *it is ordered* that, pursuant to sections 47 U.S.C. 4(i), 4(j), 9, 9A, and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 154(j), 159, 159A, and 303(r), the Report and Order *is hereby adopted*.

70. *It is further ordered* that paragraphs 21–42 of this document adopting the small satellite fee methodology *shall be effective* on September 1, 2022.

71. *It is further ordered* that the Commission *shall send* a copy of the Report and Order, including the Final Regulatory Flexibility Analysis and the Initial Regulatory Flexibility Analysis, in a report to be sent to the Congress and the Government Accountability Office pursuant to the Congressional Review Act, 5 U.S.C. 801(a)(1)(A).

72. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of the Report and Order and Final Regulatory Flexibility Analysis to the Chief Counsel for Advocacy of the Small Business Administration.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2022–13439 Filed 6–27–22; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 9

[PS Docket Nos. 20–291 and 09–14, FCC 21–80; FRS 91583]

911 Fee Diversion; New and Emerging Technologies 911 Improvement Act of 2008

Correction

In rule document 2022–13230, appearing on pages 37237–37239, in the issue of Wednesday, June 22, 2022, make the following correction:

On page 37238, in the first column, the first and second lines below the **DATES** heading should read:

''*Effective date:* This rule is effective June 22, 2022.''

[FR Doc. C1–2022–13230 Filed 6–27–22; 8:45 am]

BILLING CODE 0099–10–D

Proposed Rules

Federal Register
Vol. 87, No. 123
Tuesday, June 28, 2022

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

DEPARTMENT OF ENERGY

10 CFR Part 431

[EERE–2017–BT–STD–0007]

RIN 1904–AD82

Energy Conservation Program: Energy Conservation Standards for Commercial Refrigerators, Freezers, and Refrigerator-Freezers

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notification of availability of preliminary technical support document and request for comment.

SUMMARY: The U.S. Department of Energy (''DOE'' or ''the Department'') announces the availability of the preliminary analysis it has conducted for purposes of evaluating the need for amended energy conservation standards for commercial refrigerators, freezers, and refrigerator-freezers (''commercial refrigeration equipment'' or ''CRE''), which is set forth in the Department's preliminary technical support document (''TSD'') for this rulemaking. DOE will hold a public meeting via webinar to discuss and receive comment on its preliminary analysis. The meeting will cover the analytical framework, models, and tools used to evaluate potential standards for this equipment, the results of preliminary analyses performed by DOE, the potential energy conservation standard levels derived from these analyses (if DOE determines that proposed amendments are necessary), and other relevant issues. In addition, DOE encourages written comments on these subjects.

DATES:

Comments: Written comments and information will be accepted on or before August 29, 2022.

Meeting: DOE will hold a webinar on Monday, August 8, 2022, from 1 p.m. to 4 p.m. See section IV, ''Public Participation,'' for webinar registration information, participant instructions, and information about the capabilities available to webinar participants.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *www.regulations.gov* under docket number EERE–2017–BT–STD–0007. Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2017–BT–STD–0007, by any of the following methods:

(1) *Email: CRE2017STD0007@ee.doe.gov.* Include the docket number EERE–2017–BT–STD–0007 in the subject line of the message.

(2) *Postal Mail:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–1445. If possible, please submit all items on a compact disc (''CD''), in which case it is not necessary to include printed copies.

(3) *Hand Delivery/Courier:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW, 6th Floor, Washington, DC 20024. Telephone: (202) 287–1445. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimiles (''faxes'') will be accepted. For detailed instructions on submitting comments and additional information on this process, see section IV of this document.

To inform interested parties and to facilitate this rulemaking process, DOE has prepared an agenda, a preliminary TSD, and briefing materials, which are available on the DOE website at: *www.regulations.gov/docket/EERE-2017-BT-STD-0007.*

Docket: The docket for this activity, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at *www.regulations.gov.* All documents in the docket are listed in the *www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as those containing information that is exempt from public disclosure.

The docket web page can be found at *www.regulations.gov/docket/EERE-2017-BT-STD-0007.* The docket web page contains instructions on how to access all documents, including public comments in the docket. See section IV for information on how to submit comments through *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT:

Dr. Stephanie Johnson, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies, EE–2J, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–1943. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Ms. Kristin Koernig, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–3593. Email: kristin.koernig@*hq.doe.gov.*

For further information on how to submit a comment, review other public comments and the docket, contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

A. Authority

The Energy Policy and Conservation Act, as amended (''EPCA''),[1] authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291–6317) Title III, part C [2] of EPCA, added by Public Law 95–619, Title IV, section 441(a) (42 U.S.C. 6311–6317, as codified), established the Energy Conservation Program for Certain Industrial Equipment. This equipment includes CRE, the subject of this document. (42 U.S.C. 6311(1)(E))

EPCA established standards for certain categories of CRE (42 U.S.C. 6313(c)(2)–(4)) and directs DOE to conduct future rulemakings to determine whether to amend these standards. (42 U.S.C. 6313(c)(6)(B))

EPCA further provides that, not later than 6 years after the issuance of any final rule establishing or amending a standard, DOE must publish either a notification of determination that standards for the product do not need to be amended, or a notice of proposed rulemaking (''NOPR'') including new proposed energy conservation standards (proceeding to a final rule, as appropriate). (42 U.S.C. 6316(e)(1); 42 U.S.C. 6295(m)(1)) Not later than three years after issuance of a final determination not to amend standards, DOE must publish either a notice of determination that standards for the product do not need to be amended, or a NOPR including new proposed energy conservation standards (proceeding to a final rule, as appropriate). (42 U.S.C. 6316(e)(1); 42 U.S.C. 6295(m)(3)(B))

Under EPCA, any new or amended energy conservation standard must be designed to achieve the maximum improvement in energy efficiency that DOE determines is technologically feasible and economically justified. (42 U.S.C. 6316(e)(1); 42 U.S.C. 6295(o)(2)(A)) Furthermore, the new or amended standard must result in a significant conservation of energy. (42 U.S.C. 6316(e)(1); 42 U.S.C. 6295(o)(3)(B))

DOE is publishing this preliminary analysis to collect data and information to inform its decision consistent with its obligations under EPCA.

B. Rulemaking Process

DOE must follow specific statutory criteria for prescribing new or amended standards for covered equipment, including CRE. As noted, EPCA requires that any new or amended energy conservation standard prescribed by the Secretary of Energy (''Secretary'') be designed to achieve the maximum improvement in energy efficiency (or water efficiency for certain equipment specified by EPCA) that is technologically feasible and economically justified. (42 U.S.C. 6316(e)(1); 42 U.S.C. 6295(o)(2)(A)) Furthermore, DOE may not adopt any standard that would not result in the significant conservation of energy. (42 U.S.C. 6316(a); 42 U.S.C. 6295(o)(3))

The significance of energy savings offered by a new or amended energy conservation standard cannot be determined without knowledge of the specific circumstances surrounding a given rulemaking.[3] For example, the United States rejoined the Paris Agreement on February 19, 2021. As part of that agreement, the United States has committed to reducing greenhouse gas (''GHG'') emissions in order to limit the rise in mean global temperature.[4] As such, energy savings that reduce GHG emissions have taken on greater importance. Additionally, some covered products and equipment have most of their energy consumption occur during periods of peak energy demand. The impacts of these products on the energy infrastructure can be more pronounced than products or equipment with relatively constant demand. In evaluating the significance of energy savings, DOE considers differences in primary energy and full-fuel cycle (''FFC'') effects for different covered products and equipment when determining whether energy savings are significant. Primary energy and FFC effects include the energy consumed in electricity production (depending on load shape), in distribution and transmission, and in extracting, processing, and transporting primary fuels (*i.e.,* coal, natural gas, petroleum fuels), and thus present a more complete picture of the impacts of energy conservation standards. Accordingly, DOE evaluates the significance of energy savings on a case-by-case basis, taking into account the significance of cumulative FFC national energy savings, the cumulative FFC emissions reductions, and the need to confront the global climate crisis, among other factors.

DOE has initially determined the energy savings estimated for the candidate standard levels considered in this preliminary analysis are ''significant'' within the meaning of 42 U.S.C. 6295(o)(3)(B).

To determine whether a standard is economically justified, EPCA requires that DOE determine whether the benefits of the standard exceed its burdens by considering, to the greatest extent practicable, the following seven factors:

(1) The economic impact of the standard on the manufacturers and consumers of the products subject to the standard;

(2) The savings in operating costs throughout the estimated average life of the covered products in the type (or class) compared to any increase in the price, initial charges, or maintenance expenses for the covered products that are likely to result from the standard;

(3) The total projected amount of energy (or as applicable, water) savings likely to result directly from the standard;

(4) Any lessening of the utility or the performance of the products likely to result from the standard;

(5) The impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the standard;

(6) The need for national energy and water conservation; and

(7) Other factors the Secretary of Energy (Secretary) considers relevant.

(42 U.S.C. 6316(a); 42 U.S.C. 6295(o)(2)(B)(i)(I)–(VII))

DOE fulfills these and other applicable requirements by conducting a series of analyses throughout the rulemaking process. Table I.1 shows the individual analyses that are performed to satisfy each of the requirements within EPCA.

TABLE I.1—EPCA REQUIREMENTS AND CORRESPONDING DOE ANALYSIS

EPCA requirement	Corresponding DOE analysis
Significant Energy Savings	• Shipments Analysis • National Impact Analysis.

[1] All references to EPCA in this document refer to the statute as amended through the Energy Act of 2020, Public Law 116–260 (Dec. 27, 2020), which reflect the last statutory amendments that impact Parts A and A–1 of EPCA.

[2] For editorial reasons, upon codification in the U.S. Code, Part C was redesignated Part A–1.

[3] Procedures, Interpretations, and Policies for Consideration in New or Revised Energy Conservation Standards and Test Procedures for Consumer Products and Commercial/Industrial Equipment, 86 FR 70892, 70901 (Dec. 13, 2021).

[4] *See* Executive Order 14008, 86 FR 7619 (Feb. 1, 2021) (''Tackling the Climate Crisis at Home and Abroad'').

TABLE I.1—EPCA REQUIREMENTS AND CORRESPONDING DOE ANALYSIS—Continued

EPCA requirement	Corresponding DOE analysis
Technological Feasibility	• Energy Use Analysis. • Market and Technology Assessment. • Screening Analysis. • Engineering Analysis.
Economic Justification:	
1. Economic impact on manufacturers and consumers	• Manufacturer Impact Analysis. • Life-Cycle Cost and Payback Period Analysis. • Life-Cycle Cost Subgroup Analysis. • Shipments Analysis.
2. Lifetime operating cost savings compared to increased cost for the product.	• Markups for Product Price Analysis. • Energy Use Analysis. • Life-Cycle Cost and Payback Period Analysis.
3. Total projected energy savings	• Shipments Analysis. • National Impact Analysis.
4. Impact on utility or performance	• Screening Analysis. • Engineering Analysis.
5. Impact of any lessening of competition	• Manufacturer Impact Analysis.
6. Need for national energy and water conservation	• Shipments Analysis. • National Impact Analysis.
7. Other factors the Secretary considers relevant	• Employment Impact Analysis. • Utility Impact Analysis. • Emissions Analysis. • Monetization of Emission Reductions Benefit.[5] • Regulatory Impact Analysis.

Further, EPCA establishes a rebuttable presumption that a standard is economically justified if the Secretary finds that the additional cost to the consumer of purchasing a product complying with an energy conservation standard level will be less than three times the value of the energy savings during the first year that the consumer will receive as a result of the standard, as calculated under the applicable test procedure. (42 U.S.C. 6316(e)(1); 42 U.S.C. 6295(o)(2)(B)(iii))

EPCA also contains what is known as an ''anti-backsliding'' provision, which prevents the Secretary from prescribing any amended standard that either increases the maximum allowable energy use or decreases the minimum required energy efficiency of a covered product. (42 U.S.C. 6316(e)(1); 42 U.S.C. 6295(o)(1)) Also, the Secretary may not prescribe an amended or new standard if interested persons have established by a preponderance of the evidence that the standard is likely to result in the unavailability in the United States in any covered product type (or class) of performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as those generally available in the United States. (42 U.S.C. 6316(e)(1); 42 U.S.C. 6295(o)(4))

Additionally, EPCA specifies requirements when promulgating an energy conservation standard for a covered product that has two or more subcategories. DOE must specify a different standard level for a type or class of product that has the same function or intended use, if DOE determines that products within such group: (A) consume a different kind of energy from that consumed by other covered products within such type (or class), or (B) have a capacity or other performance-related feature which other products within such type (or class) do not have and such feature justifies a higher or lower standard. (42 U.S.C. 6316(e)(1); 42 U.S.C. 6295(q)(1)) In determining whether a performance-related feature justifies a different standard for a group of products, DOE must consider such factors as the utility to the consumer of the feature and other factors DOE deems appropriate. (*Id.*) Any rule prescribing such a standard must include an explanation of the basis on which such higher or lower level was established. (42 U.S.C. 6316(e)(1); 42 U.S.C. 6295(q)(2))

Before proposing a standard, DOE typically seeks public input on the analytical framework, models, and tools that DOE intends to use to evaluate standards for the equipment at issue and the results of preliminary analyses DOE performed for the equipment.

DOE is examining whether to amend the current standards for CRE pursuant to its obligations under EPCA. This notification announces the availability of the preliminary TSD, which details the preliminary analyses and summarizes the preliminary results of DOE's analyses. In addition, DOE is announcing a public meeting to solicit feedback from interested parties on its analytical framework, models, and preliminary results.

C. Deviation From Appendix A

In accordance with section 3(a) of 10 CFR part 430, subpart C, appendix A (''appendix A''), applicable to CRE under 10 CFR 431.4, DOE notes that it is deviating from the provision in appendix A regarding the pre-NOPR stages for an energy conservation standards rulemaking. Section 6(a)(2) of appendix A states that if the Department determines it is appropriate to proceed with a rulemaking (after initiating the rulemaking process through an early assessment), the preliminary stages of a rulemaking to issue or amend an energy conservation standard that DOE will undertake will be a framework document and preliminary analysis, or an advance notice of proposed rulemaking (''ANOPR''). DOE is opting to deviate from this step by publishing

[5] On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22–30087) granted the federal government's emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana* v. *Biden,* No. 21-cv-1074–JDC–KK (W.D. La.). As a result of the Fifth Circuit's order, the preliminary injunction is no longer in effect, pending resolution of the federal government's appeal of that injunction or a further court order. Among other things, the preliminary injunction enjoined the defendants in that case from ''adopting, employing, treating as binding, or relying upon'' the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and present monetized benefits where appropriate and permissible under law.

a preliminary analysis without a framework document. A framework document is intended to introduce and summarize the various analyses DOE conducts during the rulemaking process and requests initial feedback from interested parties. As discussed further in the following section, prior to this notification of the preliminary analysis, DOE issued an early assessment request for information (''RFI'') in which DOE identified and sought comment on the analyses conducted in support of the most recent energy conservation standards rulemaking (79 FR 17726 (March 28, 2014) (the ''March 2014 Final Rule'')). 86 FR 37708, 37710 (July 16, 2021) (the ''July 2021 RFI''). DOE provided a 45-day comment period for the early assessment July 2021 RFI. 86 FR 37708. As DOE is intending to rely on substantively the same analytical methods as in the March 2014 Final Rule, publication of a framework document would be largely redundant with the published early assessment RFI. As such, DOE is not publishing a framework document.

Section 6(d)(2) of appendix A specifies that the length of the public comment period for pre-NOPR rulemaking documents will vary depending upon the circumstances of the particular rulemaking, but will not be less than 75 calendar days. For this preliminary analysis, DOE has opted to instead provide a 60-day comment period. As stated, DOE requested comment in the July 2021 RFI on the analysis conducted in support of the March 2014 Final Rule and provided stakeholders a 45-day comment period. For this preliminary analysis, DOE has relied on many of the same analytical assumptions and approaches as used in the March 2014 Final Rule and has determined that a 60-day comment period, in conjunction with the prior 45-day comment period, provides sufficient time for interested parties to review the preliminary analysis and develop comments.

II. Background

A. Current Standards

In the March 2014 Final Rule, DOE prescribed the current energy conservation standards for CRE manufactured on and after March 27, 2017. 79 FR 17725 These standards are set forth in DOE's regulations at 10 CFR 431.66(e).

For CRE with two or more compartments (*i.e.,* hybrid refrigerators, hybrid freezers, hybrid refrigerator-freezers, and non-hybrid refrigerator-freezers), 10 CFR 431.66(e)(2) specifies that the maximum daily energy consumption for each model shall be the sum of the applicable standard of each of the compartments as specified at 10 CFR 431.66(e)(1). For wedge cases, 10 CFR 431.66(e)(3) specifies instructions to comply with the applicable standards, specified in 10 CFR 431.66(e)(1).[6] Certain exclusions to the standards at 10 CFR 431.66(e)(1) are specified at 10 CFR 431.66(f) (*i.e.,* the energy conservation standards do not apply to salad bars, buffet tables, and chef bases or griddle stands).

B. Current Process

In the July 2021 RFI, DOE published a notification that it was initiating an early assessment review to determine whether any new or amended standards would satisfy the relevant requirements of EPCA for a new or amended energy conservation standard for CRE, as well as a request for information. 86 FR 37708. Specifically, through the published notice and request for information, DOE sought data and information that could enable the agency to determine whether amended energy conservation standards would: (1) result in a significant savings of energy; (2) be technologically feasible; and (3) be economically justified. *Id.*

Comments received to date as part of the current process have helped DOE identify and resolve issues related to the preliminary analyses. Chapter 2 of the preliminary TSD summarizes and addresses the comments received.

III. Summary of the Analyses Performed by DOE

For the equipment covered in this preliminary analysis, DOE conducted in-depth technical analyses in the following areas: (1) engineering; (2) markups to determine product price; (3) energy use; (4) life-cycle cost (''LCC'') and payback period (''PBP''); and (5) national impacts. The preliminary TSD that presents the methodology and results of each of these analyses is available at *www.regulations.gov/docket/EERE-2017-BT–STD-0007*.

DOE also conducted, and has included in the preliminary TSD, several other analyses that support the major analyses or are preliminary analyses that will be expanded if DOE determines that a NOPR is warranted to propose new or amended energy conservation standards. These analyses include (1) the market and technology assessment; (2) the screening analysis, which contributes to the engineering analysis; and (3) the shipments analysis, which contributes to the LCC and PBP analysis and the national impact analysis (''NIA''). In addition to these analyses, DOE has begun preliminary work on the manufacturer impact analysis and has identified the methods to be used for the consumer subgroup analysis, the emissions analysis, the employment impact analysis, the regulatory impact analysis, and the utility impact analysis. DOE will expand on these analyses in the NOPR should one be issued.

A. Market and Technology Assessment

DOE develops information in the market and technology assessment that provides an overall picture of the market for the equipment concerned, including general characteristics of the equipment, the industry structure, manufacturers, market characteristics, and technologies used in the equipment. This activity includes both quantitative and qualitative assessments, based primarily on publicly available information. The subjects addressed in the market and technology assessment include (1) a determination of the scope of the rulemaking and equipment classes; (2) manufacturers and industry structure; (3) existing efficiency programs; (4) market and industry trends; and (5) technologies or design options that could improve the energy efficiency of the equipment.

See chapter 3 of the preliminary TSD for further discussion of the market and technology assessment.

B. Screening Analysis

DOE uses the following five screening criteria to determine which technology options are suitable for further consideration in an energy conservation standards rulemaking:

(1) *Technological feasibility.* Technologies that are not incorporated in commercial products or in working prototypes will not be considered further.

(2) *Practicability to manufacture, install, and service.* If it is determined that mass production and reliable installation and servicing of a technology in commercial products could not be achieved on the scale necessary to serve the relevant market at the time of the projected compliance date of the standard, then that technology will not be considered further.

(3) *Impacts on equipment utility or equipment availability.* If it is determined that a technology would have a significant adverse impact on the utility of the equipment for significant subgroups of consumers or would result in the unavailability of any covered equipment type with performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as equipment generally available in the United

[6] A wedge case is a CRE that forms the transition between two regularly shaped display cases. 10 CFR 431.62.

States at the time, it will not be considered further.

(4) *Adverse impacts on health or safety.* If it is determined that a technology would have significant adverse impacts on health or safety, it will not be considered further.

(5) *Unique-pathway proprietary technologies.* If a design option utilizes proprietary technology that represents a unique pathway to achieving a given efficiency level, that technology will not be considered further due to the potential for monopolistic concerns.

10 CFR 431.4; 10 CFR part 430, subpart C, appendix A, sections 6(b)(3) and 7(b).

If DOE determines that a technology, or a combination of technologies, fails to meet one or more of the listed five criteria, it will be excluded from further consideration in the engineering analysis.

See chapter 4 of the preliminary TSD for further discussion of the screening analysis.

C. Engineering Analysis

The purpose of the engineering analysis is to establish the relationship between the efficiency and cost of CRE. There are two elements to consider in the engineering analysis: the selection of efficiency levels to analyze (*i.e.,* the ''efficiency analysis'') and the determination of equipment cost at each efficiency level (*i.e.,* the ''cost analysis''). In determining the performance of higher-efficiency equipment, DOE considers technologies and design option combinations not eliminated by the screening analysis. For each equipment class, DOE estimates the manufacturer production cost (''MPC'') for the baseline as well as higher efficiency levels. The output of the engineering analysis is a set of cost-efficiency ''curves'' that are used in downstream analyses (*i.e.,* the LCC and PBP analyses and the NIA).

DOE converts the MPC to the manufacturer selling price (''MSP'') by applying a manufacturer markup. The MSP is the price the manufacturer charges its first customer, when selling into the equipment distribution channels. The manufacturer markup accounts for manufacturer non-production costs and profit margin. DOE developed the manufacturer markup by examining publicly available financial information for manufacturers of the covered equipment.

See chapter 5 of the preliminary TSD for additional detail on the engineering analysis. See chapter 12 of the preliminary TSD for additional detail on the manufacturer markup.

D. Markups Analysis

The markups analysis develops appropriate markups (*e.g.,* wholesaler markups, distributor markups, contractor markups) in the distribution chain and sales taxes to convert MSP estimates derived in the engineering analysis to consumer prices, which are then used in the LCC and PBP analysis. At each step in the distribution channel, companies mark up the price of the product to cover business costs and profit margin.

DOE developed baseline and incremental markups for each actor in the distribution chain. Baseline markups are applied to the price of products with baseline efficiency, while incremental markups are applied to the difference in price between baseline and higher-efficiency models (the incremental cost increase). The incremental markup is typically less than the baseline markup and is designed to maintain similar per-unit operating profit before and after new or amended standards.[7]

Chapter 6 of the preliminary TSD provides details on DOE's development of markups for CRE.

E. Energy Use Analysis

The purpose of the energy use analysis is to determine the annual energy consumption of CRE at different efficiencies in representative commercial buildings, and to assess the energy savings potential of increased CRE efficiency. The energy use analysis estimates the range of energy use of CRE in the field (*i.e.,* as they are actually used by consumers). The energy use analysis provides the basis for other analyses DOE performed, particularly assessments of the energy savings and the savings in consumer operating costs that could result from adoption of amended or new standards.

Chapter 7 of the preliminary TSD addresses the energy use analysis.

F. Life-Cycle Cost and Payback Period Analyses

The effect of new or amended energy conservation standards on individual consumers usually involves a reduction in operating cost and an increase in purchase cost. DOE used the following two metrics to measure consumer impacts:

- The LCC is the total consumer expense of equipment over the life of that equipment, consisting of total installed cost (MSP, distribution chain markups, sales tax, and installation costs) plus operating costs (expenses for energy use, maintenance, and repair). To compute the operating costs, DOE discounts future operating costs to the time of purchase and sums them over the lifetime of the equipment.
- The PBP is the estimated amount of time (in years) it takes consumers to recover the increased purchase cost (including installation) of more-efficient equipment through lower operating costs. DOE calculates the PBP by dividing the change in purchase cost at higher efficiency levels by the change in annual operating cost for the year that amended or new standards are assumed to take effect.

Chapter 8 of the preliminary TSD addresses the LCC and PBP analyses.

G. National Impact Analysis

The NIA estimates the national energy savings (''NES''), and the net present value (''NPV'') of total consumer costs and savings expected to result from new or amended standards at specific efficiency levels (referred to as candidate standard levels).[8] DOE calculates the NES and NPV for the potential standard levels considered based on projections of annual equipment shipments, along with the annual energy consumption and total installed cost data from the energy use and LCC analyses. For the present analysis, DOE projected the energy savings, operating cost savings, equipment costs, and NPV of consumer benefits over the lifetime of CRE sold from 2027 through 2056.

DOE evaluates the impacts of new or amended standards by comparing a case without such standards with standards case projections (''no-new-standards case''). The no-new-standards case characterizes energy use and consumer costs for each equipment class in the absence of new or amended energy conservation standards. For this projection, DOE considers historical trends in efficiency and various forces that are likely to affect the mix of efficiencies over time. DOE compares the no-new-standards case with projections characterizing the market for each equipment class if DOE adopted new or amended standards at specific energy efficiency levels for that class. For each efficiency level, DOE considers how a given standard would likely affect the market shares of equipment with efficiencies greater than the standard.

DOE uses a software package written in the Python programming language to

[7] Because the projected price of standards-compliant equipment is typically higher than the price of baseline equipment, using the same markup for the incremental cost and the baseline cost would result in higher per-unit operating profit. While such an outcome is possible, DOE maintains that in markets that are reasonably competitive it is unlikely that standards would lead to a sustainable increase in profitability in the long run.

[8] The NIA accounts for impacts in the 50 states and U.S. territories.

calculate the energy savings and the national consumer costs and savings at each standard level and in the no-new-standards case. The NIA model uses average values (as opposed to probability distributions) as inputs. Critical inputs to this analysis include shipments projections, estimated equipment lifetimes, installed costs and operating costs, annual energy consumption, the base case efficiency projection, and discount rates.

DOE estimates a combined total of 1.70 quads of site energy savings at the max- tech efficiency levels for CRE. Combined site energy savings at efficiency level 1 for all equipment classes are estimated to be 0.19 quads.

Chapter 10 of the preliminary TSD addresses the NIA.

IV. Public Participation

DOE invites public engagement in this process through participation in the webinar and submission of written comments, data, and information. After the webinar and the closing of the comment period, DOE will consider all timely-submitted comments and additional information obtained from interested parties, as well as information obtained through further analyses. Following such consideration, the Department will publish either a determination that the energy conservation standards for CRE need not be amended or a NOPR proposing to amend those standards. The NOPR, should one be issued, would include proposed energy conservation standards for the products covered by this rulemaking, and members of the public would be given an opportunity to submit written and oral comments on the proposed standards.

A. Participation in the Webinar

The time and date for the webinar meeting are listed in the **DATES** section at the beginning of this document. Webinar registration information, participant instructions, and information about the capabilities available to webinar participants will be published on DOE's website:*www.energy.gov/eere/buildings/public-meetings-and-comment-deadlines*. Participants are responsible for ensuring their systems are compatible with the webinar software.

B. Procedure for Submitting Prepared General Statements for Distribution

Any person who has an interest in the topics addressed in this document, or who is representative of a group or class of persons that has an interest in these issues, may request an opportunity to make an oral presentation at the webinar. Such persons may submit requests to speak via email to the Appliance and Equipment Standards Program at: *ApplianceStandardsQuestions@ee.doe.gov*. Persons who wish to speak should include with their request a computer file in Microsoft Word, PDF, or text (ASCII) file format that briefly describes the nature of their interest in this rulemaking and the topics they wish to discuss. Such persons should also provide a daytime telephone number where they can be reached.

C. Conduct of the Webinar

DOE will designate a DOE official to preside at the webinar and may also use a professional facilitator to aid discussion. The meeting will not be a judicial or evidentiary-type public hearing, but DOE will conduct it in accordance with section 336 of EPCA (42 U.S.C. 6306). A court reporter will be present to record the proceedings and prepare a transcript. DOE reserves the right to schedule the order of presentations and to establish the procedures governing the conduct of the webinar. There shall not be discussion of proprietary information, costs or prices, market share, or other commercial matters regulated by U.S. anti-trust laws. After the webinar and until the end of the comment period, interested parties may submit further comments on the proceedings and any aspect of the rulemaking.

The webinar will be conducted in an informal, conference style. DOE will present a general overview of the topics addressed in this rulemaking, allow time for prepared general statements by participants, and encourage all interested parties to share their views on issues affecting this rulemaking. Each participant will be allowed to make a general statement (within time limits determined by DOE), before the discussion of specific topics. DOE will allow, as time permits, other participants to comment briefly on any general statements.

At the end of all prepared statements on a topic, DOE will permit participants to clarify their statements briefly. Participants should be prepared to answer questions by DOE and by other participants concerning these issues. DOE representatives may also ask questions of participants concerning other matters relevant to this rulemaking. The official conducting the webinar/public meeting will accept additional comments or questions from those attending, as time permits. The presiding official will announce any further procedural rules or modification of the above procedures that may be needed for the proper conduct of the webinar.

A transcript of the webinar will be included in the docket, which can be viewed as described in the *Docket* section at the beginning of this document. In addition, any person may buy a copy of the transcript from the transcribing reporter.

D. Submission of Comments

DOE invites all interested parties, regardless of whether they participate in the public meeting webinar, to submit in writing no later than the date provided in the **DATES** section at the beginning of this document, comments and information on matters addressed in this notification and on other matters relevant to DOE's consideration of potential amended energy conservations standards for CRE. Interested parties may submit comments, data, and other information using any of the methods described in the **ADDRESSES** section at the beginning of this document.

Submitting comments via *www.regulations.gov*. The *www.regulations.gov* web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment itself or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. If this instruction is followed, persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (''CBI'')). Comments submitted through *www.regulations.gov* cannot be claimed as CBI. Comments received through the website will waive any CBI claims for

the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through *www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *www.regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email, hand delivery/courier, or postal mail. Comments and documents submitted via email, hand delivery/courier, or postal mail also will be posted to *www.regulations.gov*. If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information in a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via postal mail or hand delivery/courier, please provide all items on a CD, if feasible, in which case it is not necessary to submit printed copies. No faxes will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, that are written in English, and that are free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email two well-marked copies: 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. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

V. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this notification of availability of the preliminary technical support document and request for comment.

Signing Authority

This document of the Department of Energy was signed on June 21, 2022, by Kelly J. Speakes-Backman, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on June 22, 2022.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2022–13652 Filed 6–27–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0801; Project Identifier MCAI–2022–00092–T]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Airbus SAS Model A350–941 and –1041 airplanes. This proposed AD was prompted by a report indicating that the vertical stop support fitting (VSSF) of certain captain's, first officer's, and third occupant's seats could fail. This proposed AD would require modifying or replacing each affected seat, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference. This proposed AD would also limit the installation of affected parts under certain conditions. 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 August 12, 2022.

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

- *Federal eRulemaking Portal:* Go to *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 material that will be incorporated by reference (IBR) in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this material on the EASA website at *https://ad.easa.europa.eu.* You may view this material 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 in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0801.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0801; 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: Dan Rodina, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th Street, Des Moines, WA 98198, telephone and fax 206–231–3225; email *dan.rodina@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0801; Project Identifier MCAI–2022–00092–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 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 Dan Rodina, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th Street, Des Moines, WA 98198, telephone and fax 206–231–3225; email *dan.rodina@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

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2022–0014, dated January 25, 2022 (EASA AD 2022–0014) (also referred to as the MCAI), to correct an unsafe condition for all Airbus SAS Model A350–941 and –1041 airplanes.

This proposed AD was prompted by a report indicating that the VSSF of certain captain's, first officer's, and third occupant's seats could fail. The FAA is proposing this AD to address failure of the VSSF, which could lead to flight deck seat failure and unexpected seat movement under certain loading conditions, possibly resulting in flightcrew injury and reduced control of the airplane. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

EASA AD 2022–0014 specifies procedures for modifying or replacing each affected captain's, first officer's, and third occupant's seat. EASA AD 2022–0014 also limits the installation of affected seats under certain conditions. This material 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

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that 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 accomplishing the actions specified in EASA AD 2022–0014 described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2022–0014 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2022–0014 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2022–0014 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2022–0014. Service information required by EASA AD 2022–0014 for compliance will be available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0801 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this proposed AD would affect 27 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Up to 23 work-hours × $85 per hour = $1,955	* $	* $1,955	* $52,785

* The FAA has received no definitive data regarding parts costs for the seat modification or replacement.

According to the manufacturer, some or all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage for affected individuals. As a result, the FAA has included all known costs in the cost estimate.

Authority for This Rulemaking

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

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:

Airbus SAS: Docket No. FAA–2022–0801; Project Identifier MCAI–2022–00092–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by August 12, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus SAS Model A350–941 and –1041 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/furnishings.

(e) Unsafe Condition

This AD was prompted by a report indicating that the vertical stop support fitting (VSSF) of certain captain's, first officer's, and third occupant's seats could fail. The FAA is issuing this AD to address failure of the VSSF, which could lead to flight deck seat failure and unexpected seat movement under certain loading conditions, possibly resulting in flightcrew injury and reduced control of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2022–0014, dated January 25, 2022 (EASA AD 2022–0014).

(h) Exceptions to EASA AD 2022–0014

(1) Where EASA AD 2022–0014 refers to its effective date, this AD requires using the effective date of this AD.

(2) The ''Remarks'' section of EASA AD 2022–0014 does not apply to this AD.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2022–0014 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation 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 Large Aircraft Section, International Validation Branch/ manager of the certification office, send it to the attention of the person identified in paragraph (k)(2) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (j)(2) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified 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 procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(k) Related Information

(1) For EASA AD 2022–0014, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.* You may view this material 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. This material may be found in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2022–0801.

(2) For more information about this AD, contact Dan Rodina, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th Street, Des Moines, WA 98198, telephone and fax 206–231–3225; email *dan.rodina@faa.gov.*

Issued on June 22, 2022.

Christina Underwood,

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

[FR Doc. 2022–13681 Filed 6–27–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0567; Airspace Docket No. 21–ANM–67]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Rexburg-Madison County Airport, ID

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify the Class E airspace extending upward from 700 feet above the surface at Rexburg-Madison County Airport, ID. Additionally, this action proposes an administrative change to update the airport's geographic location in the legal description. These actions will ensure the safety and management of instrument flight rule (IFR) operations at the airport.

DATES: Comments must be received on or before August 12, 2022.

ADDRESSES: Send comments on this proposal to the U.S. DOT, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: (800) 647–5527, or (202) 366–9826. You must identify ''FAA Docket No. FAA–2022–0567; Airspace Docket No. 21–ANM–67,'' at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order JO 7400.11F, 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.

FOR FURTHER INFORMATION CONTACT: Nathan A. Chaffman, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–3460.

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 (U.S.C.). 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 modify Class E airspace at Rexburg-Madison County Airport, ID, to support IFR operations at the airport.

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–2022–0567; Airspace Docket No. 21–ANM–67''. 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 JO 7400.11F, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F 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 14 CFR part 71 by modifying the Class E airspace extending upward from 700 feet above the surface at Rexburg-Madison County Airport, ID. North and south extensions to the existing Class E airspace are needed to ensure containment of arriving IFR operations below 1,500 feet above the surface and departing IFR operations until they reach 1,200 feet above the surface at the airport.

Additionally, the FAA proposes an administrative modification to the airport's legal description. The geographic coordinates should be updated to match the FAA's database.

The Class E5 airspace designation is published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in FAA Order JO 7400.11, which is published yearly and becomes effective on September 15.

FAA Order JO 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 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

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

* * * * *

ANM ID E5 Rexburg, ID [Amended]

Rexburg-Madison County Airport, ID
(Lat. 43°50′02″ N, long. 111°48′18″ W)

That airspace extending upward from 700 feet above the surface within a 4-mile radius of the Rexburg-Madison County Airport, and within 2.7 miles each side of the 202° bearing extending from the 4-mile radius to 6.3 miles south of the airport, and within 2.3 miles each side of the 354° bearing extending from the 4-mile radius to 6.3 miles north of the airport.

Issued in Des Moines, Washington, on June 21, 2022.

B.G. Chew,

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

[FR Doc. 2022–13613 Filed 6–27–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0572; Airspace Docket No. 21–ANM–66]

RIN 2120–AA66

Proposed Establishment of Class E Airspace; McCarley Field, ID

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (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 McCarley Field, ID. These actions will contain all instrument flight rule (IFR) arrival and departure operations at the airport.

DATES: Comments must be received on or before August 12, 2022.

ADDRESSES: Send comments on this proposal to the U.S. DOT, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: (800) 647–5527, or (202) 366–9826. You must identify ''FAA Docket No. FAA–2022–0572; Airspace Docket No. 21–ANM–66,'' at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov*.

FAA Order JO 7400.11F, 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.

FOR FURTHER INFORMATION CONTACT: Nathan A. Chaffman, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S. 216th Street, Des Moines, WA 98198; telephone (206) 231–3460.

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 (U.S.C.). 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 at McCarley Field, Blackfoot, ID, to support IFR operations at the airport.

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–2022–0572; Airspace Docket No. 21–ANM–66''. 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 JO 7400.11F, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F 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 14 CFR part 71 by establishing Class E airspace extending upward from 700 feet above the surface at McCarley Field, ID. This airspace is intended to accommodate arriving IFR operations below 1,500 feet above the surface and departing IFR operations until they reach 1,200 feet above the surface.

The Class E5 airspace designation is published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in FAA Order JO 7400.11, which is published yearly and becomes 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 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

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

* * * * *

ANM ID E5 Blackfoot, ID [New]

McCarley Field, ID
(Lat. 43°12′33″ N, long. 112°20′59″ W)

That airspace extending upward from 700 feet above the surface within a 4.2 mile radius of the McCarley Field, and within 2 miles each side of the 030° bearing extending from the 4.2 mile radius to 7 miles northeast of the airport, and within 2.3 miles each side of the 213° bearing extending from the 4.2 mile radius to 6.4 miles southwest of the airport, and within 1.6 miles each side of the 213° bearing extending from the 4.2 mile radius to 13.6 miles southwest of the airport.

Issued in Des Moines, Washington, on June 21, 2022.

B.G. Chew,

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

[FR Doc. 2022–13612 Filed 6–27–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0569; Airspace Docket No. 21–ANM–65]

RIN 2120–AA66

Proposed Amendment of Class D and Class E Airspace; Idaho Falls Regional Airport, ID

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: A biennial review of the Idaho Falls Regional Airport was conducted, and it was discovered several amendments to the airport's existing airspace are needed. This action proposes to modify the Class D and E surface areas, the Class E airspace area designated as an extension to a Class D or Class E surface area, the Class E airspace extending upward from 700 feet above the surface, and the Class E airspace extending upward from 1,200 feet above the surface at Idaho Falls Regional Airport, ID. Additionally, this action proposes several administrative amendments to update the airport's legal descriptions. These actions will ensure the safety and management of instrument flight rule (IFR) and visual flight rule (VFR) operations at the airport.

DATES: Comments must be received on or before August 12, 2022.

ADDRESSES: Send comments on this proposal to the U.S. DOT, 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–2022–0569; Airspace Docket No. 21–ANM–65, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov*.

FAA Order JO 7400.11F, 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.

FOR FURTHER INFORMATION CONTACT: Nathan A. Chaffman, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–3460.

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 (U.S.C.). 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 modify Class D and Class E airspace at Idaho Falls Regional Airport, ID, to support IFR and VFR operations at the airport.

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–2022–0569; Airspace Docket No. 21–ANM–65.'' 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 JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F 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 14 CFR part 71 by modifying Class D and E surface areas, the Class E airspace area designated as an extension to a Class D or Class E surface area, the Class E airspace extending upward from 700 feet above the surface, and the Class E airspace extending upward from 1,200 feet above the surface at Idaho Falls Regional Airport, ID.

Class D airspace is intended to contain the point at which an aircraft executing an instrument approach procedure (IAP) can be expected to descend to less than 1,000 feet above the surface. The 1,000 foot point of the VOR RWY 3 IAP is currently outside of the lateral boundary of the airport's Class D surface area. The Class D should be extended to the southwest to contain this point. Additionally, the exclusionary language for the nearby Eastern Idaho Regional Medical Center Heliport needs to be reworded to simplify the Idaho Falls Regional Airport's Class D legal description.

The Class E surface airspace should be amended to be coincident with the Class D airspace legal description.

The Class E airspace area designated as an extension to a Class D or Class E surface area should be removed southwest of the airport. The RWY 3 VOR 1,000 foot point is proposed to be contained within the Class D surface area, and the airspace would not be needed. The Class E airspace area designated as an extension to a Class D or Class E surface area northeast of the airport is currently seven miles wide, but should have its width reduced. The extension is used to contain the VOR RWY 21 1,000 foot point, and only a 4.8 mile width is needed.

The Class E airspace extending upward from 700 feet above the surface should be removed southwest of the airport. Existing and proposed Class E airspace extending upward from 1,200 feet above the surface contains all procedure turns for the VOR RWY 3 and LOC BC RWY 3 approaches, and at least 1,500 feet exists between the highest terrain and the procedure turn altitudes. Additional Class E airspace extending upward from 700 feet above the surface is needed northeast of the airport to contain procedure turns for the ILS/LOC RWY 21 IAP, as terrain exists within 1,500 feet of the procedure turn altitude. The Class E airspace extending upward from 700 feet above the surface immediately encircling the airport needs to be expanded. This area should be increased from a 7.5-mile radius to an 8-mile radius around the airport to more appropriately contain departures and circling approaches. The existing Class E airspace extending upward from 1,200 feet above the surface over the airport consistently overlaps with adjacent airspace, creating the potential for future airspace ''traps.'' The FAA proposes to re-define the boundaries of this area to more appropriately align it with other airspace and simplify its legal description.

Finally, the FAA proposes several administrative modifications to the airport's legal descriptions. The geographic coordinates should be updated to match the FAA's database. The Class D and Class E2 legal descriptions should also be updated to replace the outdated use of the phrase ''Notice to Airmen.'' This phrase should be amended to read ''Notice to Air Missions'' to match the FAA's current definition of ''NOTAM.'' The outdated phrase ''Airport/Facility Directory'' in the Class D and Class E2 legal

descriptions should be replaced with the phrase ''Chart Supplement'' to align with current FAA publication nomenclature. Lastly, all navigational aids (NAVAID) should be removed from the Class E4 and E5 legal description text headers, as they're not required to describe the airspace areas, and the removal of the NAVAIDs simplifies the legal descriptions.

Class D, E2, E4, and E5 airspace designations are published in paragraphs 5000, 6002, 6004, and 6005, respectively, of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class D and Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

FAA Order JO 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; Feb. 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 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ANM ID D Idaho Falls, ID [Amended]

Idaho Falls Regional Airport, ID
(Lat. 43°30′49″ N, long. 112°04′15″ W)

That airspace extending upward from the surface to and including 7,200 feet MSL within a 5.4 mile radius of the airport, and within 2.4 miles each side of the 223° bearing from the airport extending from the 5.4 mile radius to 6.6 miles southwest of the airport, excluding that airspace below 5,300 feet MSL within 1 mile each side of the 126° bearing from the airport beginning 3.4 miles southeast of the airport extending to the 5.4 mile radius of the airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6002 Class E Airspace Designated as Surface Areas.

* * * * *

ANM ID E2 Idaho Falls, ID [Amended]

Idaho Falls Regional Airport, ID
(Lat. 43°30′49″ N, long. 112°04′15″ W)

That airspace extending upward from the surface within a 5.4 mile radius of the airport, and within 2.4 miles each side of the 223° bearing from the airport extending from the 5.4 mile radius to 6.6 miles southwest of the airport, excluding that airspace below 5,300 feet MSL within 1 mile each side of the 126° bearing from the airport beginning 3.4 miles southeast of the airport extending to the 5.4 mile radius of the airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. 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.

* * * * *

ANM ID E4 Idaho Falls, ID [Amended]

Idaho Falls Regional Airport, ID
(Lat. 43°30′49″ N., long. 112°04′15″ W.)

That airspace extending upward from the surface within 2.4 miles each side of the 028° bearing from the airport extending from the Class D and Class E surface area 5.4 mile radius to 7.5 miles northeast of the airport.

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

* * * * *

ANM ID E5 Idaho Falls, ID [Amended]

Idaho Falls Regional Airport, ID
(Lat. 43°30′49″ N, long. 112°04′15″ W)

That airspace extending upward from 700 feet above the surface within 8 miles of the Idaho Falls Regional Airport, and that airspace 8 miles east and 9 miles west of the 032° bearing from the airport, extending from the 8 mile radius to 28 miles northeast of the airport; and that airspace extending upward from 1,200 feet above the surface within an area bounded by a line beginning at Lat. 43°34′55″ N, long. 112°29′22″ W, to Lat. 44°19′00″ N, long. 112°04′36″ W, to Lat. 44°12′35.47″ N, long. 110°48′27.66″ W to Lat. 43°26′00″ N long. 110°57′56″ W, to Lat. 42°34′53″ N, long. 111°59''59'' W, to Lat. 42°11′3.52″ N, long. 112°00′00″ W to Lat. 42°27′00″ N long 113°22′00″ W, to Lat. 42°57′33″ N long 113°32′27″ W, thence to the point of beginning.

Issued in Des Moines, Washington, on June 15, 2022.

B.G. Chew,

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

[FR Doc. 2022–13611 Filed 6–27–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0571; Airspace Docket No. 22–ANM–46]

RIN 2120–AA66

Proposed Establishment of Class E Airspace; Christmas Valley Airport, OR

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (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 Christmas Valley Airport, OR. These actions will support the airport's transition from visual flight rules (VFR) to instrument flight rules (IFR) at the airport.

DATES: Comments must be received on or before August 12, 2022.

ADDRESSES: Send comments on this proposal to the U.S. DOT, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room

W12–140, Washington, DC 20590; telephone: (800) 647–5527, or (202) 366–9826. You must identify ''FAA Docket No. FAA–2022–0571; Airspace Docket No. 22–ANM–46,'' at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order JO 7400.11F, 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.

FOR FURTHER INFORMATION CONTACT: Nathan A. Chaffman, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–3460.

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 (U.S.C.) 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 at Christmas Valley Airport, OR, to support IFR operations at the airport.

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–2022–0571; Airspace Docket No. 22–ANM–46.'' 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 JO 7400.11F, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

Class E airspace beginning at 700 feet above the surface should be established at Christmas Valley Airport to contain departing aircraft until reaching 1,200 feet above the surface, and arriving aircraft below 1,500 feet above the surface. The proposed airspace is centered on the Christmas Valley Airport reference point, with a 14 nautical mile (NM) radius to account for rising terrain in the vicinity of the airport.

The Class E5 airspace designation is published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in FAA Order JO 7400.11, which is published annually and becomes 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 71.1 of FAA Order JO 7400.11F,

Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

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

* * * * *

ANM OR E Christmas Valley, OR [New]

Christmas Valley Airport, OR
(Lat. 43°14′11″ N, long. 120°39′53″ W)
That airspace extending upward from 700 feet above the surface within a 14-mile radius of the Christmas Valley Airport.

Issued in Des Moines, Washington, on June 21, 2022.

B.G. Chew,

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

[FR Doc. 2022–13614 Filed 6–27–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

15 CFR Part 801

[Docket No. 220616–0135]

RIN 0691–AA92

Direct Investment Surveys: BE–13, Survey of New Foreign Direct Investment in the United States

AGENCY: Bureau of Economic Analysis, Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would amend regulations of the Department of Commerce's Bureau of Economic Analysis (BEA) to set forth the reporting requirements for the BE–13, Survey of New Foreign Direct Investment in the United States (''BE–13 survey''). The BE–13 survey collects information on the acquisition or establishment of U.S. business enterprises by foreign investors, and information on expansions by existing U.S. affiliates of foreign companies. The data collected through the survey are used to measure the amount of new foreign direct investment in the United States and ensure complete coverage of BEA's other foreign direct investment statistics. BEA proposes one change to the reporting requirements of the survey that will reduce respondent burden, simplify reporting, and increase the efficiency of the data collection. This mandatory BE–13 survey is required from persons subject to the reporting requirements, whether or not they are contacted by BEA.

DATES: Comments on this proposed rule will receive consideration if submitted in writing on or before August 29, 2022.

ADDRESSES: You may submit comments, identified by RIN 0691–AA92, and referencing the agency name (Bureau of Economic Analysis), by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. For Keyword or ID, enter ''EAB–2022–0001.''
- *Email: Ricardo.Limes@bea.gov.*
- *Mail:* Direct Transactions and Positions Branch, U.S. Department of Commerce, Bureau of Economic Analysis, BE–49NI, Washington, DC 20233.
- *Hand Delivery/Courier:* Direct Transactions and Positions Branch, U.S. Department of Commerce, Bureau of Economic Analysis, BE–49NI, 4600 Silver Hill Road, Suitland, MD 20746.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in the proposed rule should be sent to BEA through any of the methods above and also to the Office of Management and Budget (OMB) by submitting comments at *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review'' or by using the search function and entering the title of the collection.

Public Inspection: All comments received are a part of the public record and will generally be posted to *https://www.regulations.gov* without change. Personal identifying information voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information. BEA will accept anonymous comments (enter N/A in required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Ricardo Limes, Chief, Direct Transactions and Positions Branch (BE–49NI), Bureau of Economic Analysis, U.S. Department of Commerce, 4600 Silver Hill Road, Washington, DC 20233; email *Ricardo.limes@bea.gov* or 301–278–9659.

SUPPLEMENTARY INFORMATION: The BE–13, Survey of New Foreign Direct Investment in the United States, is a mandatory survey conducted by BEA under the authority of the International Investment and Trade in Services Survey Act (22 U.S.C. 3101–3108).

The purpose of the BE–13 survey is to collect data on the acquisition or establishment of U.S. business enterprises by foreign investors and the expansion of existing U.S. affiliates of foreign companies to establish a new facility where business is conducted. The data collected on the survey are used to measure the amount and economic significance of new foreign direct investment in the United States and assess its impact on the U.S. economy. Foreign direct investment in the United States is defined as the ownership or control, directly or indirectly, by one foreign person (foreign parent) of 10 percent or more of the voting securities of an incorporated U.S. business enterprise, or an equivalent interest of an unincorporated U.S. business enterprise, including a branch.

This proposed rule would amend 15 CFR 801.7 to set forth the reporting requirements for the BE–13, Survey of New Foreign Direct Investment in the United States. Under this proposed rule, persons subject to the reporting requirements of the BE–13, Survey of New Foreign Direct Investment in the United States, would be required to respond, whether or not they are contacted by BEA.

The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520 (PRA).

Description of Changes

The proposed change amends the regulations for the BE–13 survey. Specifically, BEA proposes to change the reporting requirements of form BE–13E, Fiscal Year End Cost Update for Projects Originally Reported on Forms BE–13B and BE–13D. The form collects updated cost information for greenfield investments—*i.e.,* establishments or expansions of U.S. businesses by foreign investors filed on BE–13B or BE–13D forms, respectively—and is required to be filed annually until the establishment or expansion of the U.S. business enterprise is complete.

BEA proposes to limit the filing requirement of the BE–13E form to three years after the year the investment is initiated. BEA has found that this timeframe would be sufficient to collect the vast majority of the changes to total planned expenditures of greenfield investments and provide data users with insightful statistics on the ultimate cost of these investments. The proposed change would reduce respondent burden and the BEA resources needed to continue to collect and process these

updates, allowing BEA to focus resources on the featured statistics for more recent periods.

BEA will describe any proposed changes to the information collected through the survey (including the addition, deletion, and/or modification of existing questions and definitions) in a public notice and will solicit comments as part of the requirements of the Paperwork Reduction Act (PRA). Any changes to reporting requirements or significant expansions in scope of the surveys would be conducted by rulemaking.

Executive Order 12866

This proposed rule has been determined to be not significant for purposes of E.O. 12866.

Executive Order 13132

This proposed rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under E.O. 13132.

Paperwork Reduction Act

This proposed rule contains a collection-of-information requirement subject to review and approval by OMB under the PRA. The requirement will be submitted to OMB for approval as a reinstatement, with change, of a previously approved collection under OMB control number 0608–0035.

Notwithstanding any other provisions of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA unless that collection displays a currently valid OMB control number.

The BE–13 survey, as proposed, is expected to result in the filing of approximately 3,027 reports from U.S. affiliates each year. The respondent burden for this collection of information is expected to vary because of differences in company structure, size, and complexity, but is estimated to average 1.1 hours per response. The burden includes time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Thus, the total respondent burden for this survey is estimated at 3,027 hours, compared to 2,547 hours for the previous BE–13 survey estimate. The increase in burden hours is due to the increase in the overall number of respondents expected to file, partially offset by a reduction in the number of BE–13E forms expected to be filed.

We are soliciting public comments to permit the Department of Commerce/Bureau of Economic Analysis 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.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in the proposed rule should be sent to both BEA and OMB following the instructions given in the **ADDRESSES** section above.

Regulatory Flexibility Act

The Chief Counsel for Regulation, Department of Commerce, has certified to the Chief Counsel for Advocacy, Small Business Administration, under the provisions of the Regulatory Flexibility Act (RFA), 5 U.S.C. 605(b), that this proposed rulemaking, if adopted, will not have a significant economic impact on a substantial number of small entities.

Most of the U.S. business enterprises that are required to file the survey are units of multinational enterprises. For the few small businesses that are foreign-owned, BEA has attempted to keep burden to a minimum by asking only those questions that are considered essential and for which answers are likely to be readily available from the existing records of the business. The amount of information required to be reported by each U.S. business enterprise is determined by the type and cost of the transaction. When the cost of the acquisition, establishment, or expansion is less than $3 million, the U.S. business enterprise will only be required to report selected items on the BE–13 Claim for Exemption. The burden for this form is an average of 15 minutes.

Because relatively few small businesses are required to file the survey and because those that are impacted are subject to only a minimal recordkeeping burden, the Chief Counsel for Regulation certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 15 CFR Part 801

Economic statistics, Foreign investment in the United States, International transactions, Penalties, Reporting and record keeping requirements.

Paul W. Farello,

Associate Director of International Economics, Bureau of Economic Analysis.

For reasons set forth in the preamble, BEA proposes to amend 15 CFR part 801 as follows:

PART 801—SURVEY OF INTERNATIONAL TRADE IN SERVICES BETWEEN U.S. AND FOREIGN PERSONS AND SURVEYS OF DIRECT INVESTMENT

■ 1. The authority citation for 15 CFR part 801 continues to read as follows:

Authority: 5 U.S.C. 301; 15 U.S.C. 4908; 22 U.S.C. 3101–3108; E.O. 11961 (3 CFR, 1977 Comp., p. 86), as amended by E.O. 12318 (3 CFR, 1981 Comp. p. 173); and E.O. 12518 (3 CFR, 1985 Comp. p. 348).

■ 2. Revise § 801.7 to read as follows:

§ 801.7 Rules and regulations for the BE–13, Survey of New Foreign Direct Investment in the United States.

The BE–13, Survey of New Foreign Direct Investment in the United States, is conducted to collect data on the acquisition or establishment of U.S. business enterprises by foreign investors and the expansion of existing U.S. affiliates of foreign companies to establish new facilities where business is conducted. Foreign direct investment is defined as the ownership or control by one foreign person (foreign parent) of 10 percent or more of the voting securities of an incorporated U.S. business enterprise, or an equivalent interest of an unincorporated U.S. business enterprise, including a branch. BEA will describe the proposed information collection in a public notice and will solicit comments according to the requirements of the Paperwork Reduction Act (44 U.S.C. 3501–3520). All legal authorities, provisions, definitions, and requirements contained in §§ 801.1 through 801.2 and §§ 801.4 through 801.6 are applicable to this survey. Specific additional rules and regulations for the BE–13 survey are given in paragraphs (a) through (d) of this section. More detailed instructions are given on the report forms and instructions.

(a) *Response required.* A response is required from persons subject to the reporting requirements of the BE–13, Survey of New Foreign Direct Investment in the United States, contained herein, whether or not they

are contacted by BEA. Also, a person, or their agent, who is contacted by BEA about reporting in this survey, either by sending them a report form or by written inquiry, must respond in writing pursuant to this section. This may be accomplished by filing the properly completed BE–13 report (BE–13A, BE–13B, BE–13D, BE–13E, or BE–13 Claim for Exemption).

(b) *Who must report.* A BE–13 report is required of any U.S. business enterprise, except certain private funds, see exception in item (b.4.), in which:

(1) A foreign direct investment in the United States relationship is created;

(2) An existing U.S. affiliate of a foreign parent establishes a new U.S. business enterprise, expands its U.S. operations, or acquires a U.S. business enterprise, or;

(3) BEA requests a cost update (Form BE–13E) for a U.S. business enterprise that previously filed Form BE–13B or BE–13D.

(4) Certain private funds are exempt from reporting on the BE–13 survey. If a U.S. business enterprise is a private fund and does not own, directly or indirectly, 10 percent or more of another business enterprise that is not also a private fund or a holding company, it is not required to file any BE–13 report except to indicate exemption from the survey if contacted by BEA.

(c) *Forms to be filed.* Depending on the type of investment transaction, U.S. affiliates would report their information on one of five forms—BE–13A, BE–13B, BE–13D, BE–13E, or BE–13 Claim for Exemption.

(1) Form BE–13A—Report for a U.S. business enterprise when a foreign entity acquires a voting interest (directly, or indirectly through an existing U.S. affiliate) in that U.S. business enterprise including segments, operating units, or real estate; and

(i) The total cost of the acquisition is greater than $3 million; and

(ii) By this acquisition, the foreign entity now owns at least 10 percent of the voting interest (directly, or indirectly through an existing U.S. affiliate) in the acquired U.S. business enterprise.

(2) Form BE–13B—Report for a U.S. business enterprise when it is established by a foreign entity or by an existing U.S. affiliate of a foreign parent; and

(i) The expected total cost to establish the new U.S. business enterprise is greater than $3 million; and

(ii) The foreign entity owns at least 10 percent of the voting interest (directly, or indirectly through an existing U.S. affiliate) in the new U.S. business enterprise.

(3) Form BE–13D—Report for an existing U.S. affiliate of a foreign parent when it expands its operations to include a new facility where business is conducted and the expected total cost of the expansion is greater than $3 million.

(4) Form BE–13E—Report for a U.S. business enterprise that previously filed Form BE–13B or BE–13D. Form BE–13E collects updated cost information and will be collected annually for three years after the year of the establishment or expansion of the U.S. business enterprise.

(5) Form BE–13 Claim for Exemption—Report for a U.S. business enterprise that:

(i) was contacted by BEA but does not meet the requirements for filing Forms BE–13A, BE–13B, or BE–13D; or

(ii) whether or not contacted by BEA, met all requirements for filing Forms BE–13A, BE–13B, or BE–13D except the $3 million reporting threshold.

(d) *Due date.* The BE–13 forms are due no later than 45 calendar days after the acquisition is completed, the new U.S. business enterprise is established, the expansion is begun, the cost update is requested, or a notification letter is received from BEA by a U.S. business enterprise that does not meet the filing requirements for the survey.

[FR Doc. 2022–13713 Filed 6–27–22; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 314

[Docket No. FDA–2021–N–0862]

RIN 0910–AH62

Nonprescription Drug Product With an Additional Condition for Nonprescription Use

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to establish requirements for a nonprescription drug product with an additional condition for nonprescription use (ACNU). The proposed rule, if finalized, would establish requirements for a nonprescription drug product that has an ACNU that an applicant must implement to ensure appropriate self-selection or appropriate actual use, or both, by consumers without the supervision of a healthcare practitioner. The proposed rule is intended to increase options for applicants to develop and market safe and effective nonprescription drug products, which could improve public health by broadening the types of nonprescription drug products available to consumers.

DATES: Either electronic or written comments on the proposed rule must be submitted by October 26, 2022. Submit comments (including recommendations) on information collection issues under the Paperwork Reduction Act of 1995 by July 28, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 26, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–N–0862 for ''Nonprescription Drug Product with an Additional Condition for Nonprescription Use.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

Submit comments on information collection issues under the Paperwork Reduction Act of 1995 to the Office of Management and Budget (OMB) at *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. The title of this proposed collection is ''Premarket applications, postmarketing reports and recordkeeping, and labeling for Nonprescription Drug Products With an Additional Condition for Nonprescription Use.''

FOR FURTHER INFORMATION CONTACT:

With regard to the proposed rule: Chris Wheeler, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3330, Silver Spring, MD 20993–0002, 301–796–0151, *Chris.Wheeler@fda.hhs.gov.*

With regard to the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Proposed Rule

FDA is proposing to establish requirements for a nonprescription drug product with an additional condition for nonprescription use (ACNU), which is a drug product that could be marketed without a prescription if an applicant implements an additional condition to ensure appropriate self-selection or appropriate actual use, or both, by consumers without the supervision of a healthcare practitioner. Currently, nonprescription drug products are limited to drugs that can be labeled with sufficient information for consumers to appropriately self-select and use the drug product. For certain drug products, limitations of labeling present challenges for adequate communication of information needed for consumers to appropriately self-select or use the drug product without the supervision of a healthcare practitioner. The proposed rule is intended to increase options for applicants to develop and market safe and effective nonprescription drug products, which could improve public health by broadening the types of nonprescription drug products available to consumers.

B. Summary of the Major Provisions of the Proposed Rule

The proposed rule, if finalized, would establish requirements for a nonprescription drug product with an ACNU. The evidentiary standards that an application must meet under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and current FDA regulations for demonstrating safety and effectiveness would continue to apply to nonprescription drug products approved with an ACNU. This proposed rule would establish additional application requirements, labeling requirements, and postmarketing reporting requirements for a nonprescription drug product with an ACNU.

The proposed rule would establish the requirements for a new drug application (NDA) or abbreviated new drug application (ANDA) for a nonprescription drug product with an ACNU. An applicant would be required

to submit a separate application for the approval of a nonprescription drug product with an ACNU, rather than a supplement to an application approved as a prescription drug product. In addition to applicable existing application requirements, NDA applicants would also be required to describe the ACNU and submit information to support the ACNU.

The proposed rule would clarify that an ACNU would constitute a meaningful difference between a prescription drug product and a nonprescription drug product that makes the nonprescription drug product safe and effective for use without the supervision of a healthcare practitioner licensed by law to administer the drug. For instance, two drug products could have the same active ingredient, dosage form, strength, route of administration, and indication, with one made available as a nonprescription drug product with an ACNU and the other product made available only by prescription.

The proposed rule would specify that FDA would refuse to approve an NDA or ANDA for a nonprescription drug product with an ACNU if the application fails to meet the applicable requirements of proposed § 314.56 (21 CFR 314.56).

The proposed rule would establish postmarketing reporting requirements for a nonprescription drug product with an ACNU. NDA and ANDA applicants would be required to submit a report with information concerning any incident of failure in the implementation of an ACNU, such as a consumer gaining access to the drug product without fulfilling the ACNU.

C. Legal Authority

FDA's proposal to establish requirements for a nonprescription drug product with an ACNU is authorized by sections 201(n), 502, 503(b), 505, and 701(a) of the FD&C Act (21 U.S.C. 321(n), 352, 353(b), 355, and 371(a)).

D. Costs and Benefits

The proposed rule, if finalized, would establish, for any applicant, the requirements for a nonprescription drug product with an ACNU. Compared to the traditional labeling paradigm of nonprescription drug products, this approved ACNU in addition to the labeling would ensure the appropriate self-selection, appropriate use, or both, of a drug product. We expect that this proposed rule, if finalized, would expand consumer access to certain drug products in a nonprescription setting.

Greater access to drug products would allow consumers to treat certain medical conditions using nonprescription drug products with an ACNU without the supervision of a healthcare practitioner. We estimate a reduction in access costs to consumers who could transfer from a prescription to a nonprescription drug product with an ACNU. Our primary estimate for this item is $26.70 with a range of $0 to $53.40 per consumer per purchase. There may also be cost savings associated with a potential reduction in the number of repetitive meetings between FDA and industry. Our primary estimate is $55,469 per applicant with a range of $45,260 to $66,174. Government and private insurance payers may also experience cost savings because the availability of nonprescription drug products with an ACNU may decrease future medical costs and the number of submitted insurance claims. In addition, we assume that applicants would submit applications when they believe that the profits from a potential approval would exceed the costs of the application. We lack information to monetize these potential profits and costs. We do not monetize our estimates of benefits over a 10-year horizon because of the high uncertainty about the number of applicants, applications, potential approvals, the number of purchases that might occur, and consumer preferences to switch products. For details, see the Preliminary Regulatory Impact Analysis (PRIA), the Uncertainty and Sensitivity section, as well as the Appendix of the same document.

Monetized costs include a one-time cost of reading and understanding the rule for those applicants potentially interested in submitting applications for their nonprescription drug products with an ACNU. Our primary estimate of these costs equals $821 with a range of $379 and $1,264 using a 7-percent discount rate annualized over a ten-year horizon.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/acronym	What it means
ACNU	Additional Condition for Nonprescription Use.
ANDA	Abbreviated New Drug Application.
DFL	Drug Facts Labeling.
FAERS	FDA Adverse Event Reporting System.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FDA	Food and Drug Administration.
ICSR	Individual Case Safety Report.
NDA	New Drug Application.
NDC	National Drug Code.
OMB	Office of Management and Budget.
OTC	Over-the-Counter.
PDP	Principal Display Panel.
RLD	Reference Listed Drug.

III. Background

A. Need for the Regulation

Nonprescription drug products are important for the treatment of many conditions and diseases, although at present most nonprescription drug products are intended to provide temporary relief of minor symptoms or self-diagnosable, self-limited conditions and diseases, rather than chronic diseases. Unlike prescription drug products, nonprescription drug products may be accessed and used safely and effectively by consumers without the supervision of a healthcare practitioner when certain conditions are met. Currently, nonprescription drug products are limited to drugs that can be labeled with sufficient information to enable consumers to appropriately self-select and use the drug product without the supervision of a healthcare practitioner. Self-selection is the decision consumers make to use or not to use a drug product based on reading the information on the drug product labeling and applying knowledge of their personal medical history (Ref. 1). Nonprescription drug products are usually available for consumers to purchase at pharmacies, supermarkets,

or other retail locations, and from online retailers.

FDA recognizes the potential benefit of providing consumers with access to additional types of nonprescription drug products, such as some drug products that are currently available only by prescription and that treat chronic diseases or conditions. However, there are certain drug products that an applicant may seek to market on a nonprescription basis where labeling alone cannot adequately communicate the information needed for consumers to appropriately self-select, use, or both self-select and use the drug product safely and effectively without the supervision of a healthcare practitioner.

The proposed rule has the potential to broaden the types of drug products that FDA could approve as nonprescription. Under the proposed rule, when labeling alone is not sufficient to ensure that the consumer can appropriately self-select or appropriately actually use, or both, a drug product correctly in a nonprescription setting, an applicant may submit an application proposing an ACNU that a consumer must successfully fulfill to obtain the nonprescription drug product with an ACNU. For example, an applicant may submit an application for a nonprescription drug product with an ACNU that enables a consumer to treat a chronic condition that currently does not have a nonprescription treatment. The availability of nonprescription drug products with an ACNU may provide public health benefits by facilitating consumers' self-care and autonomy over their medical treatment (Ref. 2).

B. FDA's Current Regulatory Framework

There are two regulatory pathways to bring a nonprescription drug product to market in the United States: (1) the over-the-counter (OTC) drug review process under section 505G of the FD&C Act (21 U.S.C. 355h); and (2) the new drug application process under section 505 of the FD&C Act. Under the OTC drug review process, a nonprescription drug product may be marketed without an approved NDA or ANDA under section 505 of the FD&C Act if the nonprescription drug product meets the requirements of section 505G of the FD&C Act, and other applicable requirements.

FDA approves drugs as either prescription or nonprescription drug products under section 505 of the FD&C Act. A drug must be dispensed by prescription when it is not safe for use except under the supervision of a healthcare practitioner licensed by law to administer such drug product because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use (see section 503(b)(1) of the FD&C Act). If the approved drug does not meet the criteria for prescription-only dispensing, it may be marketed as nonprescription.

Section 503(b)(4)(B) of the FD&C Act provides that a drug product to which the prescription provisions of the FD&C Act do not apply (*i.e.,* a nonprescription drug product) will be deemed to be misbranded if at any time before dispensing, the label of the drug bears the ''Rx only'' symbol. Read together with section 503(b)(4)(A) of the FD&C Act, which requires prescription drug products to bear the ''Rx only'' symbol, this effectively means that absent a meaningful difference between the products, simultaneous marketing of two drug products with the same active ingredient as both a prescription and a nonprescription drug would result in one of the two products being misbranded. Examples of meaningful differences that can make a prescription drug product safe and effective only under the supervision of a healthcare practitioner licensed by law to administer such drug include the indication, strength, route of administration, dosage form, or patient population (see 83 FR 13994 at 13995, April 2, 2018; see also 70 FR 52050, September 1, 2005).

An applicant may submit an NDA for a nonprescription drug product using the pathways described in section 505(b)(1) or (2) of the FD&C Act to market a new drug product. A 505(b)(1) NDA includes full reports of investigations to demonstrate that the proposed drug product is safe and effective under the conditions prescribed, recommended, or suggested in its proposed labeling (see sections 505(d) and (b)(1) of the FD&C Act). Thus, an NDA for a nonprescription drug product must include, among other things, information to demonstrate that consumers can appropriately self-select and use the proposed drug product safely and effectively without the supervision of a healthcare practitioner. An NDA submitted under section 505(b)(2) of the FD&C Act also includes information to demonstrate that the proposed drug product is safe and effective under the conditions prescribed, recommended, or suggested in its proposed labeling, but at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use (21 U.S.C. 355(b)(2)).

Applicants may submit an ANDA using the pathway described in section 505(j) of the FD&C Act for a drug product that is a generic version of a previously approved drug product. An ANDA for a nonprescription drug product generally references a nonprescription drug product previously approved under section 505(c) of the FD&C Act (known as the RLD) and relies on the Agency's finding that the RLD is safe and effective. An ANDA generally must contain information to show that the proposed generic product (1) is the same as the RLD with respect to the active ingredient(s), conditions of use, route of administration, dosage form, strength, labeling (with certain permissible differences) and (2) is bioequivalent to the RLD. The procedures and requirements for the submission and approval of NDAs, ANDAs, and supplements to those applications are provided in part 314 (21 CFR part 314).

Generally, nonprescription drug products must be labeled with adequate directions for use so the consumer: (1) can use the drug product safely and for the purposes for which it is intended and (2) make an appropriate self-selection decision and appropriately use the nonprescription drug product (see section 502(f)(1) of the FD&C Act and § 201.5 (21 CFR 201.5)). Consumer studies can help demonstrate that the requirement for adequate directions for use is met. These studies may include label comprehension studies (Ref. 3), self-selection studies (Ref. 1), actual-use studies, and other human factors studies.

Nonprescription drug products must also comply with applicable labeling requirements under part 201 (21 CFR part 201), including the format and content requirements for OTC drug product labeling under § 201.66. Labeling created to satisfy the requirements in § 201.66 is commonly referred to as the Drug Facts labeling (DFL). The DFL is intended to enable consumers to appropriately self-select and use the nonprescription drug product safely and effectively. In addition to the DFL, FDA may approve additional labeling for nonprescription drug products.

C. History of the Rulemaking

FDA has received a number of inquiries from stakeholders about whether applications may be submitted for nonprescription drug products with one or more additional conditions that consumers must fulfill to ensure that the drug product is safe and effective for nonprescription use. As explained in detail below, FDA held a public hearing

and participated in a series of workshops convened by the Engelberg Center for Health Care Reform at the Brookings Institution (Brookings Institution) to solicit public input on expanding the approval of nonprescription drug products. FDA used stakeholder input from the public hearing and the workshops to develop the proposed rule.

1. FDA 2012 Public Hearing

In the **Federal Register** of February 28, 2012 (77 FR 12059), FDA announced a public hearing under part 15 (21 CFR part 15) entitled ''Using Innovative Technologies and Other Conditions of Safe Use to Expand Which Drug Products Can Be Considered Nonprescription'' (2012 public hearing). FDA held this public hearing on March 22 and 23, 2012, to: (1) seek input from interested stakeholders on a potential new paradigm where FDA would approve certain drug products for nonprescription use with certain conditions specific to a drug product that would otherwise require a prescription and (2) obtain information and comments on the feasibility of this paradigm and its potential benefits and costs. As part of the public hearing, FDA requested information and public comment on the types of technology that could be used; the types of conditions of safe use; and the potential impacts on pharmacies, consumers, and healthcare practitioners, as well as other issues that might arise under the paradigm. FDA received comments from various stakeholders, including consumers, private industry, healthcare professional associations, academic institutions, and patient advocacy organizations, on a broad range of topics such as: (1) access to care, (2) medication nonadherence, (3) practitioner oversight, (4) potential effect on healthcare and healthcare costs, (5) potential impact on medical conditions or diseases, (6) use of diagnostic aids and technologies as possible conditions of safe use, and (7) potential barriers to successful implementation and adoption (see Docket No. FDA–2012–N–0171).

2. Brookings Institution Workshops

The Brookings Institution convened a series of three expert workshops, based on a cooperative agreement with FDA, to seek stakeholder feedback on practical considerations for the development of a new paradigm focused on developing innovative approaches for consumers to self-select nonprescription drug products appropriately and maintain their safe and effective use and to explore potential practical strategies. Participants included a diverse set of stakeholders from both public and private sectors, including FDA and other Government agencies, healthcare professional associations, trade associations, technology developers, pharmaceutical manufacturers, healthcare professionals, academic institutions, retail pharmacy representatives, and patient advocacy organizations.

On November 8, 2012, the Brookings Institution convened the first expert workshop, ''Nonprescription Medications With Conditions of Safe Use as a Novel Solution for Undertreated Diseases or Conditions.'' This workshop explored issues and practical considerations for the development of this new paradigm (Ref. 4).

On May 9, 2013, the Brookings Institution held the second expert workshop, ''Innovative Technologies and Nonprescription Medications: Addressing Undertreated Diseases and Conditions Through Technology Enabled Self-Care.'' This workshop explored the potential for innovative technologies to facilitate safe and effective use of nonprescription drug products (Ref. 5).

On November 4, 2013, the Brookings Institution held the final expert workshop, ''Exploring Implications of the Nonprescription Drug Safe Use Regulatory Expansion Initiative on Reimbursement and Access.'' This workshop focused on assessing this paradigm's potential impact on consumer access and reimbursement (Ref. 6).

3. Innovative Approaches for Nonprescription Drug Products; Draft Guidance for Industry

In the **Federal Register** of July 18, 2018 (83 FR 33938), FDA published a notice of availability of a draft guidance entitled ''Innovative Approaches for Nonprescription Drug Products'' and established Docket No. FDA–2018–D–2281. This draft guidance describes two innovative approaches that may be useful for applicants to consider in cases where the DFL alone is not sufficient to ensure that a drug product can be used safely and effectively in a nonprescription setting. These approaches include the development of labeling in addition to the DFL and the implementation of additional conditions so that consumers can appropriately self-select and use the product.

IV. Legal Authority

FDA's proposal to establish requirements for a nonprescription drug product with an ACNU is authorized by sections 201(n), 502, 503(b), 505, and 701(a) of the FD&C Act (21 U.S.C. 321(n), 352, 353(b), 355, and 371(a)). Section 502(f) of the FD&C Act deems a drug to be misbranded unless its labeling bears adequate directions for use and adequate warnings against use in those conditions where its use may be dangerous to health, as well as adequate warnings against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users. Section 502(f) also authorizes the promulgation of regulations exempting a drug or device from the requirement to bear adequate directions for use upon a determination that such directions are not necessary for the protection of public health.

We are proposing to add an exemption for human nonprescription drug products approved with an ACNU from the requirement in section 502(f)(1) of the FD&C Act for drug products to have labeling that provides adequate directions for use (see proposed § 201.130). When labeling alone cannot provide adequate directions for use for a human nonprescription drug product, FDA may approve the nonprescription drug product with an ACNU under proposed § 314.56.

In addition, section 502(a) of the FD&C Act deems a drug to be misbranded if its labeling is false or misleading in any particular. Under section 201(n) of the FD&C Act, in determining whether labeling is misleading, there shall be taken into account (among other things), not only representations made or suggested but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences that may result from the use of the drug under the conditions of use prescribed in the labeling or under usual or customary conditions of use.

In addition, under section 505 of the FD&C Act, FDA will approve an NDA only if the drug is shown to be both safe and effective for use under the conditions prescribed, recommended, or suggested in the proposed labeling for the product. See section 505(c)(1) and (d) of the FD&C Act. If, for example, on the basis of information submitted as part of the application or on the basis of any other information before the Agency with respect to such drug, there is insufficient information to determine whether such drug is safe for use under such conditions, the Agency will not approve the drug. Section 505(j) of the FD&C Act describes the requirements

for ANDAs. In particular, section 505(j)(2)(A) specifies the information that must be included in an ANDA, and section 505(j)(4) describes the approval standard for an ANDA.

In addition, section 503(b) of the FD&C Act contains provisions regarding the marketing of a drug as either a prescription drug product or a nonprescription drug product.

Finally, section 701(a) of the FD&C Act authorizes FDA to issue regulations for the efficient enforcement of the FD&C Act.

V. Description of the Proposed Rule

We are proposing to add § 314.56 to part 314, subpart B, to establish additional application requirements for a nonprescription drug product with an ACNU under an NDA or an ANDA. The evidentiary standards that an NDA for a nonprescription drug product must meet under the FD&C Act and current FDA regulations to demonstrate the safety and effectiveness of the drug product would apply to a nonprescription drug product approved with an ACNU. An ANDA referencing a nonprescription drug product with an ACNU previously approved under an NDA may rely on FDA's finding that the listed drug product is safe and effective for use under the conditions described in the labeling. We are proposing to add § 314.125(b)(20) to part 314, subpart D, to specify that FDA would refuse to approve an NDA for a nonprescription drug product with an ACNU that does not meet the applicable requirements established in § 314.56. We are also proposing to add § 314.127(a)(15) to part 314, subpart D, to specify that FDA would refuse to approve an ANDA for a nonprescription drug product with an ACNU that does not meet the applicable requirements established in § 314.56. We are proposing to add § 314.81(b)(3)(v) to part 314, subpart B, to establish postmarketing reporting requirements for a nonprescription drug product with an ACNU. We are also proposing to add § 201.67 to part 201, subpart C, to establish labeling requirements for a nonprescription drug product with an ACNU. We are proposing to add § 201.130 to part 201, subpart D, to establish an exemption from the statutory requirement for adequate directions for use for a nonprescription drug product with an ACNU. The proposed rule is intended to increase options for applicants to develop and market safe and effective nonprescription drug products, which could improve public health by broadening the types of nonprescription drug products available to consumers. For example, FDA may approve a nonprescription drug product with an ACNU to treat a chronic condition that currently does not have nonprescription treatments.

A detailed description of each proposed section is provided in sections V.A through V.K of this document.

A. Applicability

The proposed rule would apply to NDAs and ANDAs for nonprescription drug products with an ACNU (see proposed §§ 314.56, 314.81, 314.125, 314.127, 201.67, and 201.130). Nonprescription drug products currently marketed under an approved application do not need an ACNU to ensure appropriate self-selection and appropriate actual use because FDA previously determined that labeling alone is sufficient for these drugs to be used safely and effectively without a prescription. The proposed rule would not apply to nonprescription drugs marketed under section 505G of the FD&C Act. Therefore, a requestor (as defined in section 505G(q)(3) of the FD&C Act) cannot submit a request under section 505G(b) of the FD&C Act for a nonprescription drug product with an ACNU.

B. Definitions (Proposed §§ 314.56(a) and 201.67(b))

We are proposing to define the term ''additional condition for nonprescription use'' (ACNU) as one or more FDA-approved conditions that an applicant of a nonprescription drug product must implement to ensure consumers' appropriate self-selection or appropriate actual use, or both, of the nonprescription drug product without the supervision of a healthcare practitioner if the applicant demonstrates and FDA determines that labeling alone is insufficient to ensure appropriate self-selection or appropriate actual use, or both (see proposed §§ 314.56(a) and 201.67(b)). If the ACNU is intended to address appropriate self-selection only, the labeling must enable appropriate actual use of the nonprescription drug product by consumers. Alternatively, if the ACNU is intended to address appropriate actual use only, the labeling must enable consumers to appropriately self-select the nonprescription drug product.

The proposed definition for an ACNU is intentionally broad to give applicants flexibility regarding the types of additional conditions applicants may propose and how those additional conditions can be implemented. For example, an applicant could propose an ACNU that requires a consumer, in order to purchase the nonprescription drug product, to respond with specific answers to a set of questions on a self-selection test available by either a mobile application or an automated telephone response system. An applicant may also propose that before purchasing the nonprescription drug product with an ACNU, a consumer be required to view labeling (for example, text or images in a video), that describes how to appropriately use the nonprescription drug product and to respond to questions to confirm understanding.

C. Separate Application Required for a Nonprescription Drug Product With an ACNU (Proposed § 314.56(b))

The proposed rule would not require a nonprescription drug product with an ACNU to be first marketed as a prescription drug product. However, in cases where there is an approved prescription drug product, the proposed rule would establish the requirement that a nonprescription drug product with an ACNU cannot be approved through a supplement to the approved prescription application. Rather, an applicant must submit a separate application for a nonprescription drug product with an ACNU. Although a separate application would be required, an applicant may cross reference information in its approved NDA for the prescription product and would not need to duplicate studies already conducted for and submitted in its NDA for the prescription product. As explained in Section III.B., a different applicant may submit an NDA under section 505(b)(2) of the FD&C Act, where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use. This is provided the 505(b)(2) applicant establishes that the relied upon NDA or literature is relevant to its nonprescription drug product with an ACNU and its application includes support for any differences between the applicant's proposed drug product and the listed drug on which the applicant is relying to demonstrate the safety and effectiveness of the proposed nonprescription drug product with an ACNU.

As explained in section V.E of this document, the approved prescription drug product and the approved nonprescription drug product with an ACNU are two different products and could be simultaneously marketed.

Requiring a separate application for the nonprescription drug product with an ACNU would enable continued marketing of the prescription product under the original NDA and would

allow it to serve as an RLD for ANDAs for the prescription product. Continued access to the prescription drug product, along with availability of the nonprescription drug product approved with an ACNU, would ensure greater access to needed drugs by providing flexibility in how to obtain them. For example, if a nonprescription drug product approved with an ACNU is available through a kiosk in a pharmacy, patients who do not live near a pharmacy with such a kiosk may find it easier to obtain the drug through a prescription.

Additionally, patients who prefer to continue interacting with their healthcare providers and obtain the drug by prescription would have that option. Patients who had not previously used the drug may also feel more comfortable initiating treatment and obtaining the drug with the involvement of their healthcare providers. While FDA would generally expect any technology that is used to operationalize an ACNU to be easily usable to the majority of consumers, there may be some consumers who may not be comfortable using such technology. Continued availability of the prescription drug product would provide greater flexibility in obtaining the drug and enable these patients to continue their care without potential interruption.

An applicant seeking an initial approval of an ANDA to market a nonprescription drug product with an ACNU may submit an ANDA referencing a nonprescription drug product with an ACNU previously approved under an NDA and may rely on FDA's finding that the RLD is safe and effective. This ANDA would also be required to have a separate application from an existing ANDA approved as a prescription drug product. Because the RLD nonprescription drug product with an ACNU would have a separate NDA from the NDA approved as a prescription drug product, the ANDA would be using a different NDA as its RLD from the RLD for the ANDA for the prescription product. Section 505(j)(2)(D) of the FD&C Act prohibits an applicant from amending or supplementing its ANDA to rely on a different listed drug from the listed drug identified in the ANDA submitted to FDA.

An applicant may submit an amendment, supplement, or annual report to an application for a nonprescription drug product with an ACNU, consistent with FDA regulations (§§ 314.60, 314.96, 314.70, and 314.97). An applicant seeking to make changes to an NDA or ANDA submitted for a nonprescription drug product with an ACNU that is under review by FDA would submit an amendment to the application to request a change (§§ 314.60 and 314.96). An applicant seeking to make changes to an FDA-approved NDA or ANDA for a nonprescription drug product with an ACNU would submit a supplement to the approved NDA or ANDA (§§ 314.70 and 314.97).

D. Specific Requirements for an Application for a Nonprescription Drug Product With an ACNU (Proposed § 314.56(c))

The proposed rule would establish the specific NDA and ANDA requirements for a nonprescription drug product with an ACNU (see proposed § 314.56(c)).

1. New Drug Application

In addition to applicable existing application requirements, NDA applicants would also be required to describe the ACNU and submit information to support the ACNU. Specifically, the proposed rule would require that an NDA for a nonprescription drug product with an ACNU must, when fulfilling the content and format requirements under § 314.50, include the following information about the ACNU in the application: (1) a statement regarding the purpose of the ACNU (*i.e.,* appropriate self-selection or appropriate actual use, or both, by consumers of the nonprescription drug product without the supervision of a healthcare practitioner) (see proposed § 314.56(c)(1)(i)); (2) a statement of the necessity of the ACNU (see proposed § 314.56(c)(1)(ii)); (3) a description of how the ACNU ensures appropriate self-selection or appropriate actual use, or both (see proposed § 314.56(c)(1)(iii)); (4) a description of the key elements of the ACNU (see proposed § 314.56(c)(1)(iv)); (5) adequate data or other information that demonstrate the necessity of the ACNU to ensure appropriate self-selection or appropriate actual use, or both (see proposed § 314.56(c)(1)(v)); (6) adequate data or other information that demonstrate the effect of the ACNU on the appropriate self-selection or appropriate actual use, or both (see proposed § 314.56(c)(1)(vi)); and (7) a description of the specific way the ACNU is operationalized (see proposed § 314.56(c)(1)(vii)). The first four requirements for the ACNU in the application (see proposed § 314.56(c)(1)(i) through (iv)) and the last requirement for the ACNU in the application (see proposed § 314.56(c)(1)(vii) provide statements, including explanations, descriptions, and justifications, about the ACNU; the remaining requirements for the ACNU in the application (see proposed § 314.56(c)(1)(v) through (vi)) provide data or other information to support these statements. Each of these seven requirements for the ACNU to be included in the application are further described in this section.

We are providing an example of one fictitious nonprescription drug product with an ACNU, Drug X, to provide a simplified illustration of a product that may potentially be considered under this proposed regulatory framework. We will use Drug X to explain examples of information that the applicant would submit in the NDA for a nonprescription drug product with an ACNU. This is only one type of example; many other types of ACNUs for nonprescription drug products could be possible.

Drug X is proposed as a nonprescription drug product indicated for the treatment of symptom Y in adults who have a disease-specific risk score below the threshold for developing serious side effect E when taking Drug X. As part of the nonprescription development program, the applicant conducted robust self-selection and label comprehension studies. The results of the self-selection and label comprehension studies demonstrated that consumers cannot appropriately self-select Drug X with labeling alone. FDA acknowledges these self-selection and label comprehension studies were well designed and conducted and concurs that consumers cannot self-select Drug X with labeling alone. Results of the self-selection and label comprehension studies show that, although consumers recognize that they have symptom Y, they cannot appropriately calculate their disease-specific risk score for side effect E. Therefore, the applicant proposes an ACNU for Drug X to ensure consumers' appropriate self-selection and now seeks approval of Drug X as a nonprescription drug product with an ACNU. The ACNU requires all consumers to complete a questionnaire located on a secure website created by the applicant to determine whether Drug X is appropriate for the consumer. The questionnaire has a series of questions that the consumer answers. The underlying program or other operating information used by the secure website calculates the risk score for serious side effect E using the consumer's answers and determines if the consumer has an acceptable disease-specific risk score to use Drug X. A consumer with an acceptable risk score can then either: (1) purchase Drug X on the applicant's secure website or (2) purchase Drug X

at a retail site specified by the applicant after presenting a barcoded voucher that can be printed or downloaded onto the consumer's mobile device from the applicant's secure website.

a. Statement regarding the purpose of the ACNU. The proposed rule would require the applicant to provide a statement regarding the purpose of the ACNU (see proposed § 314.56(c)(1)(i)). This statement would indicate whether the ACNU is intended for: (1) appropriate self-selection, (2) appropriate actual use, or (3) both. For example, the purpose of the ACNU for Drug X is to ensure appropriate self-selection by consumers.

b. Statement of the necessity of the ACNU. The proposed rule would require the applicant to explain why the ACNU is necessary to ensure appropriate self-selection or appropriate actual use, or both, by consumers of the nonprescription drug product (see proposed § 314.56(c)(1)(ii)). The applicant must explain why labeling alone cannot be sufficient for the purposes of meeting the approval requirements for a nonprescription drug product. The applicant may include a summary of the adequate data or other information that is submitted as part of an application for a nonprescription drug product with an ACNU, pursuant to proposed § 314.56(c)(1)(v), to explain why labeling alone cannot be sufficient.

c. Description of how the ACNU ensures appropriate self-selection or appropriate actual use, or both. The proposed rule would require the applicant to describe how the ACNU will ensure appropriate self-selection or appropriate actual use, or both, by consumers (see proposed § 314.56(c)(1)(iii)). For example, with Drug X, the applicant would describe that the ACNU requires a consumer to complete a questionnaire, located on a website, created by the applicant, that would assist in calculating a consumer's risk score for developing serious side effect E. This questionnaire would determine whether Drug X is appropriate for the consumer. The applicant may be expected, among other things, to justify the appropriateness of the self-selection questions, including the criteria and/or considerations used in calculating the risk score for a particular consumer. This may include a description of the algorithm in the underlying program or other operating information used by the website that calculates the risk score for serious side effect E to determine if the consumer has an acceptable risk score to use Drug X. The applicant would also describe how a consumer with an acceptable risk score can then purchase Drug X.

d. Description of key elements of the ACNU. The proposed rule would require the applicant to describe the key elements of the ACNU (see proposed § 314.56(c)(1)(iv)). The description of the key elements must include: (1) the additional condition(s) implemented by the applicant to be fulfilled by the consumer to be able to obtain or use the nonprescription drug product with an ACNU, (2) the labeling specifically associated with the ACNU, and (3) the criteria by which the consumer would successfully fulfill the ACNU, including a description of the specific actions to be taken by a consumer or required responses to be provided by a consumer. Labeling specifically associated with the ACNU should be annotated with each specific element of the ACNU. All labeling, including labeling specifically associated with the ACNU, should be provided in editable documents whenever possible. For example, labeling specifically associated with Drug X would include the carton and container annotated with the elements specific to the ACNU. All questions in the questionnaire would be submitted as labeling. The applicant for Drug X would describe the criteria by which the consumer would fulfill the ACNU including the questions and all potential consumer responses that would determine that Drug X was appropriate or not appropriate for the consumer.

e. Adequate data or other information that demonstrates the necessity of the ACNU to ensure appropriate self-selection or appropriate actual use, or both. The proposed rule would require an applicant to include data or other information that demonstrates the necessity of the ACNU to ensure appropriate self-selection or appropriate actual use, or both (see proposed § 314.56(c)(1)(v)). To do so, the applicant must conduct or reference adequate testing to show that labeling alone would not support the safe and effective use of the nonprescription drug product. For example, the applicant of Drug X would submit adequate data from robust self-selection studies and label comprehension studies that demonstrate that consumers could not appropriately self-select Drug X with labeling alone.

Alternatively, the applicant can submit information explaining the necessity of the ACNU for appropriate self-selection or appropriate actual use, or both, when FDA has previously signaled that labeling alone is not sufficient to ensure appropriate self-selection or appropriate actual use, or both. For example, this might apply if FDA has previously approved multiple nonprescription drug products for the same indication with a similar ACNU. The applicant is encouraged to discuss its drug development plans with FDA if the applicant has questions about whether an ACNU would be appropriate.

f. Adequate data or other information that demonstrates the effect of the ACNU on the appropriate self-selection or appropriate actual use, or both. The applicant must also submit adequate data or information that demonstrates the effect of the ACNU on the appropriate self-selection or appropriate actual use, or both, by the consumer of the nonprescription drug product (see proposed § 314.56(c)(1)(vi)). The data must show that consumers can appropriately self-select or use the drug product safely and effectively, or both, with the ACNU. For example, the applicant of Drug X would submit adequate data from robust self-selection studies that demonstrate that consumers could appropriately self-select Drug X with the ACNU.

g. Description of how the applicant will operationalize the ACNU. The proposed rule would require that the applicant describe the specific way the ACNU is operationalized (see proposed § 314.56(c)(1)(vii)). While it is important for FDA to understand how the ACNU is operationalized because this is part of achieving appropriate self-selection or use, the specific way an ACNU is operationalized is not a key element of the ACNU. The purpose of the ACNU is to enable self-selection and appropriate use without the oversight of a healthcare practitioner. The ACNU can be operationalized in different ways provided it reliably meets the objective. Alternatives to the way the ACNU is operationalized in the previous example, which involves administration of a questionnaire using a website, might include: (1) administering the questionnaire using a display screen at a pharmacy kiosk, (2) administering the questionnaire using a mobile application, and (3) administering the questionnaire using an automated telephone response system. These examples differ in the way the ACNU is operationalized (*i.e.,* how the questionnaire is being administered), but the key elements (including the questions in the questionnaire and responses that ensure appropriate self-selection) remain the same. FDA seeks comment on any unique issues that might arise for retailers or consumers based on the way the applicant operationalizes the ACNU in the previous examples, *e.g.,* in a store kiosk, online, or otherwise.

h. Additional considerations. If an NDA applicant submits an application

for a nonprescription drug product with an ACNU that proposes to use certain technologies, but FDA determines that labeling alone is sufficient to enable appropriate self-selection and appropriate actual use, FDA would refuse to approve the application for the nonprescription drug product with the ACNU (see proposed §§ 314.125(b)(20) and 314.127(a)(15)). However, FDA may approve an application for a nonprescription drug product with technologies that do not meet the definition of an ACNU. In cases where FDA determines that labeling alone is sufficient to enable appropriate self-selection and appropriate actual use, the labeling statements specifically required for a nonprescription drug product with an ACNU under this proposed rule (see proposed § 201.130) must not appear on the drug product labeling.

2. Abbreviated New Drug Application

Applicants may submit an ANDA referencing a listed drug that has been approved with an ACNU under section 505(c) of the FD&C Act and rely on FDA's previous finding that the RLD is safe and effective. The proposed rule would require that an ANDA for a nonprescription drug product with an ACNU must, when fulfilling the content and format requirements under § 314.94: (1) state the purpose of the ACNU (the same purpose as the ACNU for the RLD), (2) include information demonstrating that the key elements of the proposed ACNU are the same as the key elements of the ACNU for its RLD, and (3) include information on the way the ANDA applicant intends to operationalize the proposed ACNU. If an applicant believes the ACNU is operationalized in the same way as the RLD (*e.g.,* both use a mobile application), the ANDA must include information demonstrating the operationalization of the ACNU is the same as the RLD. If the ANDA proposes a different way to operationalize the proposed ACNU, the ANDA must include information to show that this different operationalization of the proposed ACNU achieves the same purpose as the ACNU for its RLD and the differences from the RLD are otherwise acceptable in an ANDA (see proposed § 314.56(c)(2)). As with all ANDAs, an ANDA for a nonprescription drug product with an ACNU also would be expected to be pharmaceutically equivalent and bioequivalent to its RLD and to have the same clinical effect and safety profile as its RLD when administered to patients under the conditions specified in the labeling. Information concerning the purpose of the reference product's ACNU and the description of the key elements should be available in the approval letter for the reference product or in the publicly available approval package.

The labeling for the ANDA drug product must be the same as the labeling for its RLD at the time of the ANDA's approval, except for changes required because of differences approved under a petition filed under § 314.93 or because the drug product for which an ANDA is submitted and the RLD are produced or distributed by different manufacturers (see sections 505(j)(2)(A) and (j)(4) of the FD&C Act) and §§ 314.94(a)(8) and 314.127(a)(7)).

a. Statement regarding the purpose of the ACNU. As part of the submission, an ANDA applicant would state the purpose of the ACNU (the same purpose as the ACNU for the RLD) (see proposed § 314.56(c)(2)(i)). Although an ANDA must state the purpose of the ACNU, an ANDA would not be required to include the explanation of the necessity for the ACNU or how the ACNU would ensure appropriate self-selection, appropriate actual use, or both. As a general matter, the ANDA would rely on FDA's findings of safety and effectiveness for an RLD with an ACNU.

b. Description of key elements of the ACNU. An ANDA applicant would also provide information to show that the key elements of the proposed ACNU are the same as the key elements of the ACNU approved for its RLD (see proposed § 314.56(c)(2)(ii)).

c. Description of how the applicant will operationalize the ACNU. An ANDA applicant would include information on how the ACNU would be operationalized. The proposed rule would allow ANDA applicants to operationalize its ACNU in a different way from its RLD. For instance, an ANDA applicant may consider proposing to make available on the internet a self-selection aid for its nonprescription drug product with an ACNU, whereas the self-selection aid for its RLD is made available at a physical retail store via an electronic display. Consistent with section 505(j) of the FD&C Act and our general approach to ANDAs, an ANDA would have a variety of ways to achieve the same purpose as the ACNU for its RLD. The ANDA would contain information to support that the way in which it is operationalized, as proposed, achieves the same purpose as the ACNU for its RLD and the differences from the RLD are otherwise acceptable in an ANDA (see proposed § 314.56(c)(2)(iii)). As with all ANDAs, an ANDA for a nonprescription drug product with an ACNU also would be expected to be pharmaceutically equivalent and bioequivalent to its RLD and have the same clinical effect and safety profile as its RLD when administered to patients under the conditions specified in the labeling.

FDA requests comment on the proposal to allow potential permissible differences between the NDA and the ANDA in the ways to operationalize the ACNU and how an applicant would demonstrate that the ACNU for the ANDA achieves the same purpose as the ACNU for its RLD.

As stated earlier in this proposed rule, the specific ways to operationalize the ACNU are not considered key elements of the ACNU and otherwise are not considered a condition of use of the drug product. For example, to the extent NDA applicants operationalize their ACNUs using proprietary means, ANDA applicants can use different ways than their RLD for operationalizing the ACNU (provided that the purpose of the ACNU is achieved through the same key elements).

Although FDA plays a ministerial role in listing patents in the publication ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (commonly known as the Orange Book), FDA seeks comment on whether patents claiming aspects of the ACNU for the nonprescription drug product may be submitted for listing consistent with § 314.53 and section 505(b)(1)(A)(viii) and (c)(2) of the FD&C Act. FDA seeks comments on this topic and other issues FDA should consider in implementing this proposal that will help avoid unnecessarily delaying the entry of ANDA nonprescription drug products with an ACNU to the drug market.

E. Nonprescription and Prescription Approval and Simultaneous Marketing (Proposed § 314.56(d))

FDA has interpreted the language in section 503(b)(4) of the FD&C Act to allow simultaneous marketing of drug products with the same active ingredient as prescription and nonprescription if some meaningful difference, such as indication, strength, route of administration, dosage form, or patient population, exists between the drug products that makes the prescription product safe and effective only under the supervision of a healthcare practitioner licensed by law to administer the drug (see 83 FR 13994, April 2, 2018; see also 70 FR 52050, September 1, 2005). Section 503(b)(1) of the FD&C Act requires a drug which: (1) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of

a practitioner licensed by law to dispense such drug or (2) is limited by an approved application under section 505 of the FD&C Act to use under the professional supervision of a practitioner licensed by law to administer such drug, to be dispensed only upon prescription of a practitioner licensed to administer such drug. Under section 503(b)(4)(B) of the FD&C Act, a drug, for which the prescription dispensing provisions of section 503(b)(1) of the FD&C Act do not apply, shall be deemed to be misbranded if at any time before dispensing, the label of the drug bears the ''Rx only'' symbol. Likewise, under section 503(b)(4)(A), drugs that are subject to the prescription dispensing provisions of section 503(b)(1) must bear the ''Rx only'' symbol, or else they are misbranded. This effectively means that, absent a meaningful difference between the products, simultaneous marketing of two drug products with the same active ingredient as both a prescription and a nonprescription drug product would result in one of the two products being misbranded.

Under this proposed rule, the additional condition(s) that allow a nonprescription drug product to be safely used without the supervision of a healthcare practitioner would be a meaningful difference between the prescription drug product and the nonprescription drug product with an ACNU. Therefore, under the proposed rule, a prescription drug product and a nonprescription drug product with an ACNU that contain the same active ingredient can be simultaneously marketed even if they do not have other meaningful differences, such as different indications or strengths (see proposed § 314.56(d)).

The proposed rule would require applicants seeking approval for the first time of an NDA for a nonprescription drug product with an ACNU to submit a separate NDA, rather than a supplement to an approved NDA (see proposed § 314.56(b)). The approval of a separate NDA would permit simultaneous marketing and access to the drug as both a prescription drug product and a nonprescription drug product with an ACNU. Consistent with FDA's goal of increasing options for applicants to develop and market safe and effective drugs for consumers, this proposed rule would enable continued access to the drug product as a prescription drug product, while also extending access to the drug product in the nonprescription setting with the ACNU. Even if the application holder of the NDA for the prescription drug product decides to discontinue marketing of the NDA for the prescription drug product, generic versions of the prescription drug product would be eligible for approval relying on the discontinued NDA for the prescription product as an RLD, so long as FDA determines that the NDA for the prescription product was not discontinued for reasons of safety or effectiveness (see § 314.161).

F. Refusal To Approve an Application With an ACNU (Proposed §§ 314.125(b)(20) and 314.127(a)(15))

The proposed rule would specify that FDA would refuse to approve an NDA for a nonprescription drug product with an ACNU if FDA has determined the NDA failed to meet the requirements in § 314.56 applicable to NDAs (see proposed § 314.125(b)(20)). Similarly, the proposed rule would specify that FDA would refuse to approve an ANDA for a nonprescription drug product with an ACNU that fails to meet the requirements in § 314.56 applicable to ANDAs (see proposed § 314.127(a)(15)). In addition to other reasons cited in § 314.125 or § 314.127, FDA would refuse to approve an application for a nonprescription drug product with an ACNU if FDA has determined that the applicant failed to demonstrate that labeling is insufficient to ensure consumers' appropriate self-selection or appropriate actual use, or both, of the nonprescription drug product without the supervision of a healthcare practitioner or if the applicant failed to demonstrate that its proposed ACNU is adequate to ensure appropriate self-selection or appropriate actual use, or both, by consumers without the supervision of a healthcare practitioner. We also note that under current § 314.125(b)(8), FDA may refuse to approve an NDA if the drug product's proposed labeling does not comply with the requirements for labels and labeling in part 201. This authority would permit FDA to refuse to approve an NDA with an ACNU if the labeling does not comply with labeling requirements specific to such NDAs, such as proposed §§ 201.67 and 201.130. Similarly, under current § 314.127(a)(7), FDA will refuse to approve an ANDA if its labeling is not the same as the labeling of its RLD, with certain permitted exceptions. Thus, FDA may refuse to approve an ANDA with an ACNU if its proposed labeling does not comply with labeling requirements specific to nonprescription products with an ACNU, such as proposed §§ 201.67 and 201.130.

G. Other Postmarketing Reports (Proposed § 314.81(b)(3)(v))

The proposed rule would require NDA and ANDA applicants to report to FDA information concerning any incident of failure in the implementation of an ACNU using the FDA Adverse Event Reporting System (FAERS) (see proposed § 314.81(b)(3)(v)). A failure in implementation of an ACNU would include any event that results from a deviation in an applicant's implementation of the ACNU that may cause or lead to inappropriate medication use or consumer harm, such as a consumer gaining access to the drug product without fulfilling all necessary conditions for the nonprescription drug product with an ACNU. A failure in implementation of an ACNU must be reported by the applicant whether or not the failure is associated with an adverse event. To meet these reporting requirements, applicants will likely need quality assurance systems in place to capture instances where failures in implementation of an ACNU occur. A failure in implementation of an ACNU includes the following circumstances: (1) the consumer accessed or used the drug product without successfully fulfilling the ACNU, (2) the consumer successfully fulfilled the ACNU but could not access or appropriately use the drug product in the nonprescription setting, or (3) the consumer was unable to make an attempt to fulfill the ACNU due to systematic, technological, or mechanical errors in the implementation of the ACNU. For example, for the fictitious nonprescription drug product with an ACNU Drug X (as discussed in section V.D of this document), a report would be required to be submitted to FDA if the consumer with an acceptable risk score, was unable to purchase Drug X on the applicant's website or receive a voucher from the applicant's website in order to purchase Drug X at a retail site specified by the applicant. Failure to access the drug product could result in the consumer missing doses of the drug product.

The applicant must submit a single report (an individual case safety report (ICSR) of an adverse event) describing both the failure in implementation of an ACNU and an associated adverse event when both occur and the applicant is aware of both before submitting a report. If the applicant determines that a failure of implementation of an ACNU occurred that is associated with a previously submitted ICSR of an adverse event, a followup report must be submitted to FAERS using the same unique

identification number as the original ICSR of an adverse event and must include the information concerning the failure in implementation of an ACNU as required by proposed § 314.81(b)(3)(v)(A). If the applicant receives information of an adverse event associated with a previously submitted report in FAERS of a failure in implementation of an ACNU, a followup report must be submitted to FAERS as an ICSR of an adverse event. Such followup report must use the same unique identification number as the original report in FAERS of a failure in implementation of an ACNU and must include the information concerning the adverse event as required in § 314.80(f).

A report to FAERS for a failure in implementation of an ACNU would be submitted when the applicant has at least the minimum dataset for a failure in implementation, which includes the following three elements: (1) an identifiable reporter, (2) the drug product name, and (3) a description of the failure in implementation of the ACNU. The proposed rule would require the report to include certain information that the applicant is aware of about the drug product and the initial reporter, as well as a narrative summary of the failure in implementation of an ACNU and a description of the action initiated or completed to address the failure in implementation of an ACNU. The applicant would be required to submit a report for each failure in implementation of an ACNU as soon as possible but no later than 15 calendar days from the date when the applicant has acquired the minimum dataset for a report of a failure in implementation of an ACNU. Additionally, if an applicant obtains or otherwise receives any new information about previously submitted reports about the failure in implementation of an ACNU, the applicant would be required to investigate the new information, assess the relationship or impact of the new information on the initial report, and submit followup reports as soon as possible but no later than 15 calendar days after obtaining the new information. Proposed § 314.81(b)(3)(v)(C) would require the report to be submitted to FDA in an electronic format that FDA can process, review, and archive unless a waiver has been requested and granted. To better enable FDA to assess compliance with reporting requirements and to facilitate FDA's inspection of related records, we are proposing to require an applicant to maintain for a period of 10 years the records of all reports of failures in implementations of an ACNU and associated adverse events known to the applicant (proposed § 314.81(b)(3)(v)(D)).

FDA seeks specific comment on the burden and benefits of submitting an individual report to FDA for each individual failure in implementation of an ACNU encountered by a consumer resulting from the same cause of failure, as opposed to a single, consolidated report for all such failures. For example, there could be a situation where an ACNU involves administration of a questionnaire using a pharmacy kiosk, and the kiosk screen malfunctions, preventing multiple consumers from fulfilling the ACNU because they cannot complete the questionnaire on the kiosk screen. We are seeking comment on the benefits and burdens in this type of situation of submitting individual reports for each consumer affected by the malfunction versus one single, consolidated report for all consumers affected.

H. General Labeling Requirements (Proposed § 201.67(c))

The proposed rule would clarify that a nonprescription drug product with an ACNU must comply with all applicable regulatory requirements for nonprescription drug products, including those under part 201. Specifically, the applicant must comply with the existing content and format requirements for nonprescription drug products in § 201.66, known as the DFL (see proposed § 201.67(c)(1)). As required in § 201.66(c)(6), the labeling for all nonprescription drug products must contain directions for use under the heading ''Directions.'' The proposed rule would require the labeling for all nonprescription drug products approved with an ACNU to include the following statement, as specified in proposed § 201.130(a)(1), as the first statement under the heading ''Directions'': ''To check if this drug is safe for you, go to [insert where or how consumers can find information about the ACNU; for example, applicant's website, applicant's phone number, or specific retail location] and [insert action to be taken by consumer]. Do not take this drug without completing this step.'' This initial statement would be followed by the other required information in § 201.66(c)(6). This proposed statement would alert consumers that the nonprescription drug product with an ACNU has a requirement that must be fulfilled to ensure safe and effective use. The proposed statement would further remind the original purchaser and alert persons other than the original purchaser that the product is not suitable for all individuals and that consumers should carefully examine any labeling accompanying the nonprescription product with an ACNU before using the product.

As stated previously, FDA may currently approve labeling for nonprescription drug products in addition to the DFL, and this would continue if the proposed rule is finalized (see proposed § 201.67(c)(2)). For example, FDA could approve information leaflets or other documents contained inside the carton or container for a nonprescription drug product, including for a nonprescription drug product with an ACNU.

A list of questions to be answered by the consumer in a self-selection aid could be labeling necessary to effectively implement the ACNU. All labels and other written, printed, or graphic matter that are necessary to effectively implement the ACNU (*e.g.,* questions associated with a self-selection aid) would be considered to accompany the nonprescription drug product and, therefore, would meet the definition of labeling under the FD&C Act.

Approved labeling for a nonprescription drug product with an ACNU must be available to consumers at the time of purchase and use as required in section 502(c) of the FD&C Act. In general, we believe that the applicant should describe in their application the process for ensuring consumers have access to the approved labeling prior to fulfilling the ACNU.

I. Format Requirements for Required ACNU Statement (Proposed § 201.67(d))

The proposed rule would require that the statement specified in § 201.130(a)(2) meet specific format requirements (see proposed § 201.67(d)). This statement must be visible to consumers at the time of purchase and use. Additionally, the statement would alert persons that may have access to the drug product (*e.g.,* family members in the purchaser's home), including the individual who originally purchased the product, that these nonprescription drug products are not suitable for all individuals and should only be used after fulfilling the ACNU. The proposed rule would require that the statement appear on the principal display panel (see § 201.60) and the immediate container surface that the consumer is most likely to view when seeking information about the drug product (see proposed § 201.67(d)(1)). If the immediate container is a bottle, the statement must appear on the surface that the consumer would most likely consider to be the front of the bottle. If

the immediate container is a blister card, the statement must appear on the blister card surface that the consumer would most likely view when removing the drug product from the blister card. If the blister card contains more than one blister unit, the statement would not need to be included on each blister unit of a blister card. However, the statement must remain intact and be readable on the blister card when the drug product is removed from each blister unit.

The proposed rule would require that the statement be prominently presented in boldface and black type in a yellow background banner (see proposed § 201.67(d)(2) and (3)). No other information or statement may be included in the yellow background banner. The hue of the yellow color in the background banner must be a shade that provides a high contrast with the black type of the statement. The font size of the statement would be at least 25 percent as large as the font size of the largest printed words on the container surface that the consumer would most likely view when seeking information about the drug product; in no case could the font size be smaller than 12 point type (1 point = 0.0138 inches) (see proposed § 201.67(d)(4)). For containers where the size would render compliance with this requirement impractical, the applicant would be able to request an exception to the minimum font size requirement (see proposed § 201.67(d)(5)). However, FDA would not determine an exception is warranted if the statement is not prominent in relation to other elements on the container surface containing the statement.

J. Exemption From Adequate Directions for Use (Proposed § 201.130)

Consistent with the proposed definition of ACNU, a drug product can only be approved with an ACNU if the applicant demonstrates and FDA determines that labeling alone is insufficient to ensure appropriate self-selection or appropriate actual use, or both. Therefore, it is not possible for these products to be labeled with adequate directions for use under section 502(f)(1) of the FD&C Act, as defined in § 201.5. The proposed rule would exempt a nonprescription drug product with an ACNU from the statutory requirement to be labeled with adequate directions for use, provided that certain conditions are met. Specifically, a nonprescription drug product approved with an ACNU under section 505(c) or (j) of the FD&C Act would be exempt from section 502(f)(1) if the product contains the labeling required under proposed § 201.130(a) and the ACNU is implemented by the applicant as approved by FDA in the application (see proposed § 201.130). FDA is proposing this exemption to the requirement for adequate directions for use for a nonprescription drug product with an ACNU because we have determined that the labeling and the ACNU are sufficient to ensure consumers' appropriate self-selection and actual use of the nonprescription product without the supervision of a healthcare practitioner. Therefore, adequate directions for use, as required by section 502(f)(1) of the FD&C Act and § 201.5, would not be necessary for the protection of the public health.

The proposed rule would require that the following statement appear as the first direction under the heading ''Directions'' in the labeling, as required in § 201.66(c)(6): ''To check if this drug is safe for you, go to [insert where or how consumers can find information about the ACNU; for example, applicant's website, phone number, or specific retail location] and [insert action to be taken by consumer]. Do not take this drug without completing this step.'' (See proposed § 201.130(a)(1).) The applicant would include information to inform consumers where the additional condition would be found and explain the additional condition that the consumer must fulfill. For example, ''To check if this drug is safe for you, go to *www.XYZCompany.com* and take the self-selection questionnaire. Do not take this drug without completing this step.'' The statement would be followed by the other information required in § 201.66(c)(6). FDA is specifically seeking comment on the content of the statements and the ability of these statements to sufficiently inform consumers that the product is a nonprescription drug product with an ACNU and how consumers would fulfill the ACNU.

The proposed rule would also require that the following statement appear on the immediate container label and, if one exists, the outside container or wrapper of the retail package: ''You must complete an extra step to see if this drug is safe for you before you use it. Do not take this drug without completing this step. See the Drug Facts labeling for more information.'' (See proposed § 201.130(a)(2).) This statement must meet the specific format requirements as specified in proposed § 201.67(d). The statement would remind the original purchaser and alert persons other than the original purchaser that these nonprescription drug products are not suitable for all individuals and should only be used after fulfilling the ACNU. FDA is specifically seeking comment on whether this statement would sufficiently alert consumers that this product is a nonprescription drug product with an ACNU.

The proposed rule would require the ACNU to be implemented by the applicant under the conditions set forth in the approved application for the nonprescription drug product with an ACNU to be exempt from the requirement to be labeled with adequate directions for use (see proposed § 201.130(b)).

K. Misbranding (Proposed § 201.67(e))

As noted immediately above, the proposed rule would exempt a nonprescription drug product with an ACNU from the requirement to be labeled with adequate directions for use under section 502(f)(1) of the FD&C Act, provided that certain conditions are met (see proposed § 201.130). If a nonprescription drug product with an ACNU is made available to consumers without the labeling specified in proposed § 201.130(a) or the ACNU is not implemented by the applicant as approved by FDA in the application, the drug product would be misbranded under section 502(f)(1) of the FD&C Act (see proposed § 201.67(e)).

As discussed in sections V.H and V.I of this document, the proposed rule would include specific labeling requirements for a nonprescription drug product with an ACNU. If the nonprescription drug product with an ACNU is made available to consumers without the specific required labeling, the product would also be misbranded under section 502(a) of the FD&C Act, which provides that a drug's labeling must not be false or misleading in any particular (see proposed § 201.67(e)). Under section 201(n) of the FD&C Act, in determining whether labeling is misleading, there shall be taken into account (among other things), not only representations made or suggested but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences that may result from the use of the drug under the conditions of use prescribed in the labeling or under usual or customary conditions of use. The required labeling statements described in proposed § 201.130(a) are intended to inform consumers that the product is a nonprescription drug product with an ACNU; to instruct consumers on how to fulfill the ACNU; and to remind the original purchaser (and alert persons other than the original purchaser) that

the nonprescription drug product is not suitable for all individuals and should only be used after fulfilling the ACNU. Thus, failure of a nonprescription drug product approved with an ACNU to bear the required labeling statements described in proposed § 201.130(a) would constitute a failure to reveal material facts about the product or with respect to consequences that might result from its use and would misbrand the product.

In addition, a nonprescription drug product with an ACNU could be misbranded under other provisions of section 502 of the FD&C Act. For example, in certain circumstances, such a drug may be misbranded under section 502(j) if the product does not meet the requirements of this proposed rule.

Under the proposed rule, a nonprescription drug product with an ACNU must only be made available to the consumer after the ACNU has been fulfilled by the consumer. It is a prohibited act under section 301(a) of the FD&C Act to introduce or deliver for introduction into interstate commerce any drug that is misbranded (21 U.S.C. 331(a)). It is also a prohibited act under section 301(k) of the FD&C Act to do any act with respect to a drug if such act is done while such drug is held for sale after shipment in interstate commerce and results in the drug being misbranded.

Additionally, a nonprescription drug product approved with an ACNU would be an unapproved new drug if it is made available to consumers without the ACNU. With certain limited exceptions not relevant here, it is a violation of sections 301(d) and 505(a) of the FD&C Act to introduce or deliver for introduction into interstate commerce an unapproved new drug.

VI. Proposed Effective Date

We propose that a final rule based on this proposed rule become effective 60 days after the date the final rule publishes in the **Federal Register**.

VII. Preliminary Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us 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, and other advantages; distributive impacts; and equity). This proposed rule has been designated by the Office of Information and Regulatory Affairs as a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. This rule would establish the requirements for a nonprescription drug product with an ACNU. We cannot anticipate the number of applicants that would submit applications or the types of drug products that would be covered under such applications. However, we estimate the costs for any applicant to read and understand the rule would likely range between 0.04 percent and 0.14 percent of the gross receipts of very small applicants. Therefore, we propose to certify that the proposed rule, if finalized, would not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''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.'' The current threshold after adjustment for inflation is $165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

The proposed rule, if finalized, would establish the requirements for a nonprescription drug product with an ACNU. Compared to the traditional labeling paradigm of nonprescription drug products, this approved ACNU in addition to the labeling would ensure the appropriate self-selection, appropriate use, or both, of a drug product. We expect this rule could expand consumer access to certain drug products in a nonprescription setting.

Table 1 shows our quantified benefits. We estimate a reduction in access costs to consumers who could transfer from a prescription to a nonprescription drug product with an ACNU. Our primary estimate for this item is $26.70 with a range of $0 to $53.40 per consumer per purchase. We also quantify the value of the potential reduction in the number of repetitive meetings with sponsors that the rule could eliminate, which occur during the approval process. This estimate includes benefits to FDA and industry. Our primary estimate is $55,469 per applicant with a range of $45,260 to $66,174. We do not monetize our estimates of benefits over a 10-year horizon because of the high uncertainty about number of applicants, applications, potential approvals, the number of purchases that might occur, and consumer preferences to switch products but present estimates in the uncertainty section of the full preliminary analysis of economic impacts.

Although an applicant would incur the development and postmarketing, including reporting of failure in the implementation of the ACNU and recordkeeping costs, we assume that applicants submit applications when they believe that their expected profits from the approval will exceed the costs of the application. We present a range of these potential development and postmarketing costs in the appendix of the complete economic analysis. However, we lack information to monetize these costs over a 10-year horizon and request comment or data on these potential costs.

Monetized costs include a one-time cost of reading and understanding the rule. Using a 7-percent discount rate, the primary estimate, annualized over a 10-year horizon, equals $821 with a range of $379 to $1,264. These annualized costs are the same using a 3-percent discount rate.

Government and private insurance payers may experience positive transfers because consumers may decrease future medical costs and the number of submitted insurance claims. Earlier access to drug products would allow consumers to treat medical conditions using nonprescription drug products with an ACNU without the supervision of a healthcare practitioner.

TABLE 1—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Benefits:							
Annualized Monetized $millions/year.							
Annualized Quantified				2018			Quantified reduction in access costs per consumer purchase range from $0.0 to $53.40, and a primary estimate of $26.70.
				2018			Quantified reduction in meetings between FDA and applicants range from $45,260 to $66,174 per applicant, and a primary estimate of $55,469.
Qualitative.							
Costs:							
Annualized	$0.0	$0.0	$0.0	2018	7	10 years	Reading and understanding one-time costs.
Monetized $millions/year	$0.0	$0.0	$0.0	2018	3	10 years.	
Annualized.							
Quantified.							
Qualitative							Affected firms would incur costs to develop and submit applications.
Transfers:							
Federal					7		
Annualized Monetized $millions/year					3		
From/To	From:			To:			
Other					7		
Annualized Monetized $millions/year					3		
From/To	From:			To:			Potential benefits to government and private payors if access cost of medications decline.

Effects:
State, Local or Tribal Government: No estimated effect.
Small Business: The estimated costs to very small potential applicants in this industry would range from 0.04 percent to 0.14 percent of gross receipts.
Wages: No estimated effect.
Growth: No estimated effect.

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 7) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations*.

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) and (k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). A description of these provisions is given in the *Description* section below, with an estimate of the annual reporting, recordkeeping, and third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Premarket applications, postmarketing reports and recordkeeping, and labeling for Nonprescription Drug Products With an Additional Condition for Nonprescription Use.

Description: We are revising requirements applicable to NDA and ANDA applicants of nonprescription drug products with an ACNU (collectively, respondents). If finalized, the proposed rule will modify information collections applicable to regulations in part 314 governing new and abbreviated new drug application submissions and drug labeling provisions in part 201 pertaining to nonprescription drug products.

Description of Respondents: The respondents are: (1) for NDA and ANDA

submissions, an applicant who submits an NDA (including a 505(b)(2) application) or an ANDA under part 314 to obtain FDA approval of a nonprescription drug with an ACNU; (2) for failure of implementation of an ACNU reporting and recordkeeping, any person who holds an approved NDA (including a 505(b)(2) application) or an approved ANDA that includes an ACNU; and (3) for labeling, any person who holds an approved NDA (including a 505(b)(2) application) or an approved ANDA that includes an ACNU.

We estimate the burden of the information collection as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN; OMB CONTROL NO. 0910–0001[1]

Information collection activity; 21 CFR part 314 (application for FDA approval to market a new drug)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Submission of separate application for nonprescription drug product with an ACNU; § 314.56(b) and (c)	6	1	6	320	1,920
Other postmarketing reports; submission of each individual consumer affected by a failure in implementation of an ACNU; § 314.81	6	25	150	40	6,000
Total			156		7,920

[1] There are no capital, or operating or maintenance costs associated with the information collection.

NDA and ANDA Submissions

Based on our experience with information collection associated with current NDA and ANDA submissions, we estimate six applications for a nonprescription drug product with an ACNU will be submitted annually by six respondents. Based on Broad Agency Announcement proposals that set forth the number of hours anticipated to produce study reports for submission to us, we assume it will take an average of 320 hours per application for both NDA and ANDA applicants to prepare and submit the information required for applications for nonprescription drugs with an ACNU (in addition to meeting the general NDA or ANDA requirements under §§ 314.50 and 314.94, already approved in OMB control number 0910–0001).

Reports of a Failure in Implementation of an ACNU

We estimate six respondents will each submit 25 reports to FDA for an individual failure in implementation of an ACNU under § 314.81(b)(3)(v). We assume an average of 40 hours per response for each applicant, for a total of 6,000 hours annually. As noted in the preamble of the proposed rule, we are also soliciting comments on the alternative reporting mechanism requiring the applicant to submit a single, consolidated report for all consumers affected by the same failure in implementation of an ACNU rather than a report for each individual impacted by the same failure in implementation of an ACNU. If that alternative is implemented in the final rule, we estimate that the number of reports per respondent would be reduced from 25 annual responses per respondent to 1 per year per respondent.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN; OMB CONTROL NO. 0910–0001 [1]

Information collection; 21 CFR part 314 (applications for FDA approval to market a new drug)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Requirements for failures in implementation of an ACNU; § 314.81	6	25	150	8	1,200

[1] There are no capital, or operating or maintenance costs associated with the information collection.

Based on our experience with postmarket recordkeeping requirements, we assume an average burden of 8 hours of recordkeeping for each report and therefore have calculated 1,200 hours annually.

TABLE 4—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN; OMB CONTROL NO. 0910–0340 [1]

Information collection activity; 21 CFR part 201, subpart C (format and content requirements for over-the-counter drug product labeling)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Disclosure of information on the principal display panel or within Drug Facts Labeling; § 201.66 (including statements specified in § 201.130(a)(1))	6	1	6	15	90
Additional ACNU labeling—§ 201.67	6	1	6	9	54
Total			12		144

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Labeling for Nonprescription Drugs With an ACNU

Based on our experience with NDA and ANDA submissions, we estimate six respondents will each submit an application for a nonprescription drug product with an ACNU, each becoming subject to all nonprescription labeling regulations in (21 CFR part 201, subpart C). This includes the requirements for statements of identity and net contents (§§ 201.61 and 201.62) which appear on the principal display panel (PDP) (defined by § 201.60); the Drug Facts labeling (DFL) requirements of § 201.66, as part of which the respondents must also include (where applicable) labeling to satisfy sodium, calcium, magnesium, and potassium labeling requirements (§§ 201.64, 201.70, 201.71, and 201.72); and the statements proposed to be required by § 201.130(a)(1). (The proposed requirement in § 201.130(a)(2) to place a specified ACNU statement on the product PDP is not included in the definition of *collection of information* under the PRA and is therefore not subject to review and approval by OMB. See 5 CFR 1320.3(c)(2). These products may also have additional labeling beyond the DFL requirements (§ 201.67(c)(2)).

Estimating six respondents will each have one new, approved drug that must comply with PDP and DFL labeling requirements, including statements specified in § 201.130(a)(1), and assuming compliance with these disclosures will require 15 hours per drug, we calculate a total of 90 hours annually. Additionally, we estimate six respondents will each have one new nonprescription drug product approved with an ACNU that contains additional labeling requirements, for a total of six annual responses. Based on our experience with nonprescription labeling requirements, we assume an average burden per response of 9 hours, for a total of 54 hours annually.

To ensure that comments on this information collection are received, OMB recommends that written comments be submitted through *reginfo.gov* (see **ADDRESSES**). All comments should be identified with the title of the information collection.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. These information collection requirements will not be effective until FDA publishes a final rule, OMB approves the information collection requirements, and the rule goes into effect. FDA will announce OMB approval of these requirements in the **Federal Register**.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would 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. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XII. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA, Guidance for Industry, ''Self-Selection Studies for Nonprescription Drug Products,'' April 2013 (available at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*).
2. Chang J., A. Lizer, I. Patel, et al., ''Prescription to Over-the-Counter Switches in the United States,'' *Journal of Research in Pharmacy Practice,* vol. 5(3), pp. 149–154, doi:10.4103/2279–042X.185706. Available at: *https://www.jrpp.net/text.asp?2016/5/3/149/185706.*
3. FDA, Guidance for Industry, ''Label Comprehension Studies for Nonprescription Drug Products,'' August 2010 (available at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*).
4. Engelberg Center for Health Care Reform at the Brookings Institution, ''Expert Workshop: Nonprescription Medications With Conditions of Safe Use as a Novel Solution for Undertreated Diseases or Conditions,'' November 8, 2012 (available at *https://www.brookings.edu/events/nonprescription-medications-with-conditions-of-safe-use-as-a-novel-solution-for-undertreated-diseases-or-conditions*), accessed July 30, 2021.
5. Engelberg Center for Health Care Reform at the Brookings Institution, ''Expert Workshop: Innovative Technologies and Nonprescription Medications: Addressing Undertreated Diseases and Conditions through Technology Enabled Self-Care,'' May 9, 2013 (available at *https://www.brookings.edu/events/innovative-technologies-and-nonprescription-medications-addressing-undertreated-diseases-and-conditions-through-technology-enabled-self-care*), accessed July 30, 2021.
6. Engelberg Center for Health Care Reform at the Brookings Institution, ''Expert Workshop: Exploring Implications of the Nonprescription Drug Safe Use Regulatory Expansion (NSURE) Initiative on Reimbursement and Access,'' November 4, 2013 (available at *https://www.brookings.edu/events/exploring-implications-of-the-nonprescription-drug-safe-use-regulatory-expansion-nsure-initiative-on-reimbursement-and-access*), accessed July 30, 2021.
7. FDA, Preliminary Regulatory Impact Analysis; Initial Regulatory Flexibility Analysis; Unfunded Mandates Reform Act Analysis, Nonprescription Drug Product With an Additional Condition for Nonprescription Use; Proposed Rule (available at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm*).

List of Subjects

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR parts 201 and 314 be amended as follows:

PART 201—LABELING

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

Authority: 21 U.S.C. 321, 331, 343, 351, 352, 353, 355, 358, 360, 360b, 360ccc, 360ccc–1, 360ee, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

■ 2. Add § 201.67 to subpart C to read as follows:

§ 201.67 Labeling requirements for a nonprescription drug product with an additional condition for nonprescription use (ACNU).

(a) *Scope.* This section sets forth labeling requirements for a nonprescription drug product with an ACNU.

(b) *Definition.* The following definition applies to this section:

(1) *Additional condition for nonprescription use* (ACNU) means one or more FDA-approved conditions that an applicant of a nonprescription drug product must implement to ensure consumers' appropriate self-selection or appropriate actual use, or both, of the nonprescription drug product without the supervision of a healthcare practitioner if the applicant demonstrates and FDA determines that labeling alone is insufficient to ensure appropriate self-selection or appropriate actual use, or both.

(2) [Reserved]

(c) *General labeling requirements.* (1) A nonprescription drug product with an ACNU must comply with applicable labeling requirements for nonprescription drug products under this part, including the format and content requirements for nonprescription drug product labeling under § 201.66 and the statements specified in § 201.130(a).

(2) A nonprescription drug product with an ACNU may also be approved with additional labeling that supplements the format and content requirements for nonprescription drug product labeling under § 201.66.

(d) *Format requirements for required ACNU statement.* The statement specified in § 201.130(a)(2) must meet all format requirements as follows:

(1) The statement must appear on the principal display panel (see § 201.60) and the immediate container surface that the consumer is most likely to view when seeking information about the drug product. If the immediate container is a bottle, the statement must appear on the surface that the consumer is most likely to consider the front of the bottle. If the immediate container is a blister card (including a card that contains more than one blister unit), the statement must appear on the blister card surface that the consumer would most likely view when removing the drug product from the blister card. If the blister card contains more than one blister unit (*e.g.,* perforated blister card where individual blister units can be separated from one another), the statement does not need to be included on each blister unit of a blister card. However, the statement must remain intact and be readable on the blister card when the drug product is removed from each blister unit.

(2) The statement must appear in boldface and black type.

(3) The statement must appear in a yellow background banner. No other information or statements may be included within the yellow background banner.

(4) The statement must be in one of the following font sizes, whichever is greater:

(i) At least 25 percent as large as the font size of the largest printed words on the principal display panel and immediate container; or

(ii) At least 12 point font (1 point = 0.0138 inches).

(5) An applicant may request an exception to the minimum font size requirement specified in paragraph (d)(4) of this section for containers where its size would render compliance with this requirement impractical. FDA may allow such an exception upon request by an applicant if FDA determines an exception is warranted.

(e) *Misbranding.* A nonprescription drug product with an ACNU is misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) if—

(1) It is made available without the labeling specified in § 201.130(a); or

(2) The ACNU is not implemented by the applicant as approved by FDA in the application.

■ 3. Add § 201.130 to subpart D to read as follows:

§ 201.130 Exemption from adequate directions for use for a nonprescription drug product with an additional condition for nonprescription use.

A nonprescription drug product approved under section 505(c) or 505(j) of the Federal Food, Drug, and Cosmetic Act with an ACNU as defined in § 201.67(b) is exempt from section 502(f)(1) if all the following conditions in paragraphs (a) and (b) of this section are met:

(a) The label of the drug:

(1) Bears, as the first direction under the ''Directions'' heading required in § 201.66(c)(6), the statement ''To check if this drug is safe for you, go to [insert where or how consumers can find information about the ACNU; for example, applicant's website, applicant's phone number, or specific retail location] and [insert action to be taken by consumer]. Do not take this drug without completing this step.'' The statement must be followed by the other information required in § 201.66(c)(6).

(2) Bears, in the form and manner required by § 201.67(d), the statement ''You must complete an extra step to see if this drug is safe for you before you use it. Do not take this drug without completing this step. See the Drug Facts labeling for more information.''

(3) Complies with other applicable labeling requirements for nonprescription drug products under this part, including the format and content requirements for nonprescription drug product labeling under § 201.66.

(b) The additional condition for nonprescription use is implemented by the applicant under the conditions set forth in the approved application.

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 4. The authority citation for part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 355a, 355f, 356, 356a, 356b, 356c, 356e, 360cc, 371, 374, 379e, 379k–1.

■ 5. Add § 314.56 to subpart B to read as follows:

§ 314.56 Nonprescription drug product with an additional condition for nonprescription use (ACNU).

(a) *Definition.* The following definition applies to this section:

(1) *Additional condition for nonprescription use* (ACNU) means one or more FDA-approved conditions that an applicant of a nonprescription drug product must implement to ensure consumers' appropriate self-selection or appropriate actual use, or both, of the nonprescription drug product without the supervision of a healthcare practitioner if an applicant demonstrates and FDA determines that labeling alone is insufficient to ensure appropriate self-selection or appropriate actual use, or both.

(2) [Reserved]

(b) *Separate application required for a nonprescription drug product with an ACNU.* An applicant must submit a separate application for a nonprescription drug product with an ACNU. Initial approval for a nonprescription drug product with an ACNU cannot be obtained through a supplement to an approved application.

(c) *Specific requirements for an application for a nonprescription drug product with an ACNU.* The applicant must submit an application that complies with the following requirements:

(1) *New drug application (NDA).* When fulfilling the content and format requirements under § 314.50, an NDA for a nonprescription drug product with an ACNU must include—

(i) A statement regarding the purpose of the ACNU: ensure appropriate self-selection or appropriate actual use, or both, by consumers of the nonprescription drug product with an ACNU without the supervision of a healthcare practitioner;

(ii) A statement regarding the necessity of the ACNU;

(iii) A description of how the ACNU ensures appropriate self-selection or appropriate actual use, or both;

(iv) A description of the key elements of the ACNU, including:

(A) The additional condition implemented by the applicant to be fulfilled by the consumer to obtain the nonprescription drug product with an ACNU;

(B) The labeling specifically associated with the ACNU; and

(C) The criteria by which the consumer would successfully fulfill the ACNU, including a description of the specific actions to be taken by a consumer or required responses to be provided by a consumer;

(v) Adequate data or other information that demonstrates the necessity of the ACNU to ensure appropriate self-selection or appropriate actual use, or both;

(vi) Adequate data or other information that demonstrates the effect of the ACNU on the appropriate self-selection or appropriate actual use, or both; and

(vii) A description of the specific way the ACNU is operationalized.

(2) *Abbreviated new drug application (ANDA).* When fulfilling the content and format requirements under § 314.94, an ANDA for a nonprescription drug product with an ACNU must—

(i) State the purpose of the ACNU;

(ii) Include information demonstrating that the key elements of the proposed ACNU are the same as the key elements of the ACNU for its reference listed drug (RLD); and

(iii) Include information on the way the ACNU would be operationalized. If an applicant believes the ACNU is operationalized in the same way as the RLD, include information demonstrating that the ACNU is operationalized in the same way as the RLD. If a different way to operationalize the proposed ACNU is used, include information to show that this different way to operationalize the proposed ACNU achieves the same purpose as the ACNU for its RLD and that the differences from the RLD are otherwise acceptable in an ANDA.

(d) *Simultaneous marketing of nonprescription and prescription products.* An ACNU constitutes a meaningful difference between a nonprescription drug product and a prescription drug product, such that a prescription drug product and a nonprescription drug product with an ACNU may be simultaneously marketed even if there is not another meaningful difference between the two products that makes the nonprescription drug product safe and effective for use without the supervision of a healthcare practitioner licensed by law to administer the drug (*e.g.,* a different active ingredient, indication, strength, route of administration, dosage form, or patient population).

■ 6. Amend § 314.81 by adding paragraph (b)(3)(v) to read as follows:

§ 314.81 Other postmarketing reports.

* * * * *

(b) * * *

(3) * * *

(v) *Report of failure in the implementation of an additional condition for nonprescription use.* The applicant must submit a report when a failure in the implementation of an additional condition for nonprescription use (ACNU) for a nonprescription drug product occurs. A report of a failure in implementation of an ACNU includes any event that results from a deviation in an applicant's implementation of the ACNU that may cause or lead to inappropriate medication use or consumer harm. All failures in implementation of an ACNU must be reported to the FDA Adverse Event Reporting System (FAERS), whether or not the failure in implementation of an ACNU is associated with an adverse event. If an applicant becomes aware of both a failure in implementation of an ACNU and an associated adverse event before the submission to FAERS, a single individual case safety report (ICSR) that describes both the failure in implementation of an ACNU and the associated adverse event must be submitted and must contain the information as required in § 314.80(f) and paragraph (b)(3)(v)(A) of this section. If a previously submitted report to FAERS describes only a failure in implementation of an ACNU or a previously submitted ICSR reports only an adverse event, and the submitter subsequently becomes aware of an associated adverse event or associated failure in implementation of an ACNU, the submitter must supplement the original report to FAERS with the new information. The supplement must include the information required in § 314.80(f) or paragraph (b)(3)(v)(A) of this section, as applicable.

(A) *Content.* The report must include the following for a failure in implementation of an ACNU:

(*1*) *Required information.* The name, address, email, and telephone number of the applicant; an identifiable reporter; the drug product name; and the description of the failure in implementation of the ACNU.

(*2*) *Additional information, if known.* In addition, the report must include the following information, if known:

(*i*) Drug product strength; National Drug Code (NDC); lot number; and NDA or ANDA number.

(*ii*) Initial reporter information including name, address, and telephone number of the initial reporter.

(*iii*) Unique case identification number, which must be the same in the initial report and any subsequent followup report(s).

(*iv*) Narrative summary of failure in implementation of an ACNU, including the date of failure in implementation of an ACNU (or best estimate); the date the failure in implementation of an ACNU was reported to applicant; the location of failure in implementation of an ACNU, including business name and contact information; and whether any of the following circumstances occurred: The consumer accessed or used the drug product without successfully fulfilling the ACNU; the consumer successfully fulfilled the ACNU but could not access or use the drug product; or the consumer was unable to make an attempt to fulfill the ACNU; and

(*v*) The remedial action taken or completed to address the failure in implementation of an ACNU, including the type of remedial action initiated or completed (for example, repair, replace, recall, inspection, modification, or adjustment) and a description of how the applicant will prevent failures of the same nature in the future.

(B) *Submission.* (*1*) The applicant must submit the report for each failure in implementation of an ACNU as soon as possible but no later than 15 calendar days from the date when the applicant has acquired the minimum dataset for a failure in implementation of an ACNU.

(*2*) The applicant must also investigate any new information it obtains or otherwise receives about previously submitted reports and assess the relationship or impact of the new information on the initial report. The applicant must submit followup reports as soon as possible but no later than 15 calendar days after obtaining the new information.

(C) *Electronic format for submissions.* (*1*) The report must be submitted to FDA in accordance with § 314.80(g).

(*2*) An applicant may request, in writing, a waiver of the requirements in paragraph (b)(3)(v)(C)(*1*) of this section in accordance with § 314.90 or § 314.99.

(D) *Recordkeeping.* The applicant must maintain for a period of 10 years, the records of all reports of failures in implementation of an ACNU and associated adverse events known to the applicant, including raw data and any correspondence relating to a report of a failure in implementation of an ACNU.

* * * * *

■ 7. Amend § 314.125 by adding paragraph (b)(20) to read as follows:

§ 314.125 Refusal to approve an NDA.

* * * * *

(b) * * *

(20) For an NDA for a nonprescription drug product with an additional condition for nonprescription use under § 314.56, if FDA has determined the application failed to meet the requirements in § 314.56 applicable to NDAs.

* * * * *

■ 8. Amend § 314.127 by adding paragraph (a)(15) to read as follows:

§ 314.127 Refusal to approve an ANDA.

(a) * * *

(15) For an ANDA for a nonprescription drug product with an additional condition for nonprescription use under § 314.56, if FDA has determined the application failed to meet the requirements in § 314.56 applicable to ANDAs.

* * * * *

Dated: June 15, 2022.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2022–13309 Filed 6–27–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 20

[REG–130975–08]

RIN 1545–BI11

Guidance Under Section 2053 Regarding Deduction for Interest Expense and Amounts Paid Under a Personal Guarantee, Certain Substantiation Requirements, and Applicability of Present Value Concepts

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document proposes to amend existing regulations issued under section 2053 of the Internal Revenue Code (Code). The proposed regulations provide guidance on the proper use of present-value principles in determining the amount deductible by an estate for funeral expenses, administration expenses, and certain claims against the estate. In addition, the proposed regulations provide guidance on the deductibility of interest expense accruing on tax and penalties owed by an estate, and interest expense accruing on certain loan obligations incurred by an estate. The proposed regulations also amend and clarify the requirements for substantiating the value of a claim against an estate that is deductible in certain cases. Finally, the proposed regulations provide guidance on the deductibility of amounts paid under a decedent's personal guarantee. The proposed regulations will affect estates of decedents seeking to deduct funeral expenses, administration expenses, and/or certain claims against the estate under section 2053. This document also provides a notice of a public hearing on these proposed regulations.

DATES: Electronic or written comments must be received by September 26, 2022. The public hearing is being held by teleconference on October 12, 2022, at 10 a.m. EST. Requests to speak and outlines of topics to be discussed at the public hearing must be received by September 26, 2022. If no outlines are received by September 26, 2022, the public hearing will be cancelled. Requests to attend the public hearing must be received by 5:00 p.m. EST on October 7, 2022. The telephonic hearing will be made accessible to people with disabilities. Requests for special assistance during the telephonic hearing must be received by October 6, 2022.

ADDRESSES: Commenters are strongly encouraged to submit public comments electronically. Submit electronic submissions via the Federal eRulemaking Portal at *www.regulations.gov* (indicate IRS and REG–130975–08). Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The IRS expects to have limited personnel available to process comments that are submitted on paper through the mail. The IRS will publish any comments submitted electronically, and to the extent practicable, comments submitted on paper to the public docket. Send paper submissions to CC:PA:LPD:PR (REG–130975–08), Room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

For those requesting to speak during the hearing, send an outline of topic submissions electronically via the Federal eRulemaking Portal at *www.regulations.gov* (indicate IRS and REG–130975–08).

Individuals who want to testify (by telephone) at the public hearing must send an email to *publichearings@irs.gov* to receive the telephone number and access code for the hearing. The subject line of the email must contain the regulation number REG–130975–08 and the word TESTIFY. For example, the subject line may say: Request to TESTIFY at Hearing for REG–130975–08. The email should include a copy of the speaker's public comments and outline of topics. Individuals who want to attend (by telephone) the public hearing must also send an email to *publichearings@irs.gov* to receive the telephone number and access code for the hearing. The subject line of the email must contain the regulation number REG–130975–08 and the word ATTEND. For example, the subject line may say: Request to ATTEND Hearing for REG–130975–08. To request special assistance during the telephonic hearing, contact the Publications and Regulations Branch of the Office of Associate Chief Counsel (Procedure and Administration) by sending an email to *publichearings@irs.gov* (preferred) or by telephone at (202) 317–5177 (not a toll-free number).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Karlene Lesho or Melissa Liquerman at (202) 317–6859; concerning the submission of comments, the hearing, or to be placed on the building access list to attend the hearing, Regina Johnson at (202) 317–6901 (not toll-free numbers) or by sending an email to *publichearings@irs.gov.*

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

I. Overview

This document contains proposed amendments to the Estate Tax Regulations (26 CFR part 20) under section 2053.

Section 2001(a) imposes a tax on the transfer of the taxable estate of every decedent who was at death a citizen or resident of the United States. Section 2051 defines the taxable estate as the value of the gross estate less the deductions provided for in sections 2053 through 2058. Section 2031(a) describes the value of the gross estate of the decedent as including the value at the time of the decedent's death of all property, real or personal, tangible or intangible, wherever situated.

Under section 2053(a), for Federal estate tax purposes, the value of the

taxable estate is determined by deducting from the value of the gross estate the following amounts that are allowable by the laws of the jurisdiction, whether within or without the United States, under which the estate is being administered: (1) funeral expenses, (2) administration expenses, (3) claims against the estate, and (4) unpaid mortgages on, or any indebtedness in respect of, property where the value of the decedent's interest therein, undiminished by such mortgage or indebtedness, is included in the value of the gross estate.

Final regulations amending the regulations under section 2053 (TD 9468) were published in the **Federal Register** (74 FR 53652) on October 20, 2009 (2009 Final Regulations). The 2009 Final Regulations generally limit the deduction for claims and expenses to the amount actually paid in settlement or satisfaction of that item, with exceptions for certain ascertainable amounts, claims against the estate, and indebtedness. *See* § 20.2053–1(d)(1) and (4); § 20.2053–4(b) and (c); and § 20.2053–7. The 2009 Final Regulations also reserve § 20.2053–1(d)(6) to provide future guidance on the issue of the appropriate application of present-value principles in determining the amount deductible under section 2053. These proposed regulations address this issue. In addition, these proposed regulations provide or clarify rules under section 2053 addressing the deductibility of interest expense accruing on tax and penalties owed by an estate, the deductibility of interest expense accruing on certain loan obligations incurred by an estate, requirements for substantiating the value of a claim against an estate that is deductible under § 20.2053–4(b) or (c), and the deductibility of amounts paid under a decedent's personal guarantee.

II. Application of Present-Value Principles to Amount Deductible Under Section 2053

A. Issue Background

''Present value'' is a widely accepted principle of accounting for the time value of money. If a payor can defer paying a dollar until a later time, the payor can earn income on that dollar until the date of payment. The longer a payor can defer payment, the more income the payor potentially can earn. Taxpayers, the IRS, and courts regularly employ present-value principles for valuation and for other income tax and transfer tax purposes. *See, e.g.,* section 1274(b), §§ 1.642(c)–6, 20.7520–1, and 25.2512–5; *Simpson et al.* v. *United States,* 252 U.S. 547 (1920); *Commissioner* v. *Estate of Sternberger,* 348 U.S. 187 (1955).

The deduction allowable under section 2053 eliminates from taxation under section 2001 that portion of the gross estate that the estate expends or necessarily will expend in paying certain expenses and liabilities of the estate and certain claims against the estate. The expended portions of the gross estate do not pass to the decedent's legatees, beneficiaries, or heirs and, therefore, are not subject to the estate tax. The 2009 Final Regulations implement these principles in determining the amount an estate may deduct for certain claims and expenses. Section 20.2053–1(d)(1) generally limits the deduction under section 2053 for certain claims and expenses to the total amount actually paid in settlement or satisfaction of that item. Section 20.2053–1(d)(2) clarifies that events occurring after the date of a decedent's death will be taken into consideration in determining the allowable deduction under section 2053.

Applying present-value principles to determine the allowable deduction under section 2053 for payments made or to be made after an extended period following a decedent's death is consistent with the principles underlying section 2053 and the approach of the 2009 Final Regulations. By limiting the deduction to the discounted amount of a payment or payments made or to be made after an extended period following the decedent's death, the gross estate is reduced by a more accurate measure of the amounts not passing to the heirs and legatees. Accordingly, the Department of the Treasury (Treasury Department) and the IRS have determined that limiting the amount deductible to the present value of the amounts paid after an extended post-death period will more accurately reflect the economic realities of the transaction, the true economic cost of that expense or claim, and the amount not passing to the beneficiaries of the estate. Moreover, consistent with the 2009 Final Regulations, this approach treats the date of payment of the otherwise deductible expense or claim as a post-death event properly taken into account under section 2053.

Rules applying present-value principles to certain long-term obligations were provided in proposed regulations (REG–143316–03) published in the **Federal Register** (72 FR 20080) on April 23, 2007 (2007 Proposed Regulations), which preceded the issuance of the 2009 Final Regulations. Specifically, the 2007 Proposed Regulations required the computation of the present value of future payments for a decedent's noncontingent recurring obligation, such as a noncontingent recurring obligation to pay an annuity amount under a property settlement agreement. *See* § 20.2053–4(b)(7)(i) of the 2007 Proposed Regulations. However, that rule did not apply to contingent recurring obligations. Rather, amounts payable for a decedent's contingent recurring obligation became deductible only as amounts were paid by the estate in satisfaction of the claim and the amount deductible equaled the dollar amount actually paid. No computation of present value factored into the amount deductible for such obligations. *See* § 20.2053–4(b)(7)(ii) of the 2007 Proposed Regulations.

The preamble to the 2009 Final Regulations indicated that the Treasury Department and the IRS found persuasive criticism of those proposed rules by commenters suggesting they produced an inconsistent and inequitable result. The 2009 Final Regulations clarified that the amount payable pursuant to a decedent's noncontingent recurring obligation is deemed ascertainable with reasonable certainty and, hence, deductible in advance of payment under the rule in § 20.2053–1(d)(4), while the amount payable pursuant to a decedent's contingent recurring obligation is not ascertainable with reasonable certainty and, hence, the amount deductible is limited to amounts actually paid by the estate in satisfaction of the claim. *See* § 20.2053–4(d)(6). However, the 2009 Final Regulations removed the present-value limitation applicable only to noncontingent recurring obligations and reserved § 20.2053–1(d)(6) to provide future guidance on the issue.

With regard to a decedent's obligations that satisfy the requirements for deductibility as described in the preceding paragraph, whether such obligations are recurring or nonrecurring, there is no persuasive technical or policy basis for limiting the application of present-value principles to payments made or to be made only under noncontingent obligations. Because discounting the amounts actually paid or to be paid in the future to determine the present value of the payments is consistent with the purpose of section 2053 of reducing the gross estate only by the amounts not passing to the heirs and legatees, these proposed regulations propose to incorporate present-value principles in determining the amount deductible under section 2053. The proposed regulations will apply present-value principles consistently to expenses and claims (whether contingent or noncontingent)

that are deductible under section 2053. The mechanics of applying present-value principles to expenses and claims, including expenses and claims that are deductible in advance of payment, are described in section II.B of this Background and Explanation of Provisions.

B. Explanation of Provision

The Treasury Department and the IRS propose to amend the regulations under section 2053 to incorporate present-value principles in determining the amount deductible under section 2053 for claims and expenses (excluding unpaid mortgages and indebtedness deductible under § 20.2053–7). The Treasury Department and the IRS recognize, however, that estates often cannot pay every deductible claim and expense within a short time after the decedent's death and that sound tax administration should balance the benefit of more accurately determining the amounts not passing to the beneficiaries of an estate garnered from applying present-value principles with the administrative burden of applying those principles to deductible claims and expenses that occur during a reasonable period of administration of the estate. The Treasury Department and the IRS understand that a significant percentage of estates pay most, if not all, of their ordinary estate administration expenses during the three-year period following the decedent's date of death. This three-year period takes into account a reasonable time for administering and closing the estate. The Treasury Department and the IRS note that a reasonably short period of time between the decedent's death and the payment of a claim prevents the lack of a present-value discount from significantly distorting the value of the net (distributable) estate. Applying present-value principles in computing the deductible amount of those claims and expenses paid more than three years after the decedent's death strikes an appropriate balance between benefits and burdens.

Accordingly, the Treasury Department and the IRS propose to amend the regulations under section 2053 to require the discounting to present value of certain amounts paid or to be paid in settlement or satisfaction of certain claims and expenses in determining the amount deductible under section 2053. Specifically, the rule in these proposed regulations requires calculating the present value of the amount of a deductible claim or expense described in section 2053(a) and § 20.2053–1(a) that is not paid or to be paid on or before the third anniversary of the decedent's date of death, which three-year period the proposed regulations define as the ''grace period.'' The proposed regulations provide the general formula for calculating the present value of such amounts and state that the discount rate to be used in the calculation is the applicable Federal rate determined under section 1274(d) for the month in which the decedent's date of death occurs, compounded annually. The length of time from the decedent's death to the date of payment or expected date of payment will determine whether the Federal rate applicable to that amount is the Federal mid-term rate or the Federal long-term rate. The proposed regulations provide that any reasonable assumptions or methodology in regard to time period measurements may be used in calculating the present value. In addition, the proposed regulations require a supporting statement to be filed with the Form 706 showing any calculations of present value.

The proposed regulations explain how to calculate present value when the amount of a claim or expense is deductible in advance of the payment of such amount, as under §§ 20.2053–1(d)(4) and 20.2053–4(b) and (c). The proposed regulations provide that the expected date or dates of payment will be used in computing present value and that the expected date or dates of payment will be determined by making a fair and reasonable estimate using all information reasonably available to the taxpayer. For amounts deductible under § 20.2053–4(b) and (c), the proposed regulations provide that the expected date or dates of payment must be identified in a written appraisal document. Consistent with the rule in § 20.2053–1(d)(2), which takes into consideration events occurring during the post-death period described in that section, the proposed regulations also provide that the computation of present value is subject to adjustment if the actual date of payment differs from the estimate used.

III. Deductibility of Interest Expense as Administration Expense

A. Issue Background

Section 2053(a)(2) allows an estate to deduct from the value of the gross estate the amount of administration expenses that are allowable by the law of the jurisdiction in which the estate is being administered. In some cases, interest expense incurred by an estate may be a deductible administration expense under section 2053(a)(2) if the facts support a finding that the expense satisfies the requirements of section 2053 and the regulations thereunder. Several statutory and regulatory provisions are relevant to the deductibility of interest as an administration expense under section 2053(a)(2).

First, effective for decedents dying after December 31, 1997, section 2053(c)(1)(D) provides that, ''no deduction shall be allowed under [section 2053] for any interest payable under section 6601 on any unpaid portion of the [Federal estate tax] for the period during which an extension of time for payment of such tax is in effect under section 6166.''

Second, § 20.2053–3(a) provides that the amounts deductible from a decedent's gross estate as administration expenses under section 2053(a)(2) are limited to such expenses that actually and necessarily are incurred in the administration of the decedent's estate. The expenses contemplated in the law are those that are associated with the settlement of an estate and the transfer of the property of the estate to individual beneficiaries or to a trustee. Expenditures not essential to the proper settlement of the estate, but incurred for the individual benefit of the heirs, legatees, or devisees, may not be taken as deductions.

Third, § 20.2053–1(b)(2) provides that only expenses that are bona fide in nature are deductible under section 2053. Section 20.2053–1(b)(2) applies to any amounts deductible under section 2053(a) and (b), including deductible administration expenses.

The issue of the extent to which and the circumstances under which interest expense satisfies the requirements for a deductible administration expense under section 2053(a)(2) and the regulations thereunder is longstanding. Over the past half century, a number of litigated cases and sub-regulatory published guidance items have provided some clarity on the legal issues surrounding the ability to deduct, as an administration expense under section 2053(a)(2), interest accruing on deferred tax and penalties and on loan obligations incurred by an estate. Litigation on this fact-driven issue continues in regard to interest accruing on loan obligations incurred by an estate.

The Treasury Department and the IRS consider it appropriate to amend the regulations under section 2053 to address specifically the issue of interest expense as a deductible administration expense under section 2053(a)(2). In particular, the Treasury Department and the IRS propose to address interest expense accruing after the death of the decedent on any unpaid portion of tax

or penalties and on a loan obligation incurred by the estate to pay estate taxes or other estate expenses.

B. Explanation of Provisions

1. Interest Accruing on Unpaid Tax and Penalties

In general, interest is payable at the underpayment rate in section 6621 on (i) any amount of unpaid Federal tax, and (ii) any unpaid additions to tax, additional taxes, and penalties (such interest referred to in this preamble as ''section 6601 interest'' and such additions to tax, additional taxes, and penalties collectively referred to in this preamble as ''penalties''). *See* section 6601(a) and (e)(2). However, interest payable under section 6601 on unpaid estate tax deferred under section 6166 (which includes interest accruing on any such deferred payment during any period when an extension of time for payment is in effect under section 6161(a)(2)(B) with respect to that payment) (referred to in this preamble as ''section 6166 interest'') is subject to a more favorable interest rate under section 6601(j), and section 2053(c)(1)(D) provides that such interest is not deductible. The statutory prohibition of a deduction for section 6166 interest does not apply to ''non-section 6166 interest,'' defined for purposes of this preamble as any section 6601 interest other than section 6166 interest and interest payable on any unpaid portion of state tax and penalties pursuant to state law. Thus, non-section 6166 interest that accrues on and after the decedent's date of death may qualify as a deductible administration expense under section 2053(a)(2).

To determine the deductibility of non-section 6166 interest accruing on and after the decedent's date of death, the existing regulatory requirements in §§ 20.2053–1(b)(2) and 20.2053–3(a) apply. Non-section 6166 interest satisfies the ''bona fide'' requirement in § 20.2053–1(b)(2) because such interest accrues pursuant to either Federal or state law. Non-section 6166 interest may satisfy the ''actually and necessarily incurred'' requirement in § 20.2053–3(a), but such determination depends on the facts and circumstances.

Non-section 6166 interest may accrue on and after the date of a decedent's death on unpaid estate tax in connection with an extension granted under section 6161 (but not under section 6161(a)(2)(B)) or a deferral elected under section 6163. A section 6161 extension is granted upon a showing of reasonable cause for extending the time for payment. A section 6163 deferral is appropriate when the value of a reversionary or remainder interest is includible in the gross estate, but such value is not immediately available for payment of the estate tax. The nature of both section 6161 extensions and section 6163 deferrals indicates they are based on a demonstrable need to defer payment. Accordingly, the Treasury Department and the IRS have determined that interest payable under section 6601 on unpaid estate tax in connection with an extension under section 6161 or a deferral under section 6163 is necessarily incurred in the administration of the estate.

Non-section 6166 interest may accrue on and after the date of a decedent's death on unpaid tax and penalties in connection with an underpayment of tax or a deficiency (as that term is defined in section 6211). In many cases, such interest and the underlying underpayment of tax or deficiency is attributable to the reasonable exercise of an executor's fiduciary duties in administering the estate, as may occur in cases involving legitimate disagreements with the IRS, inadvertent errors, or reasonable reliance on a qualified professional. The Treasury Department and the IRS have determined that, generally, such interest is actually and necessarily incurred in the administration of the estate. However, the Treasury Department and the IRS are concerned that there are some circumstances in which such interest expense would not satisfy the ''actually and necessarily incurred'' requirement in § 20.2053–3(a). For instance, when non-section 6166 interest accrues on unpaid tax and penalties in connection with an underpayment of tax or deficiency and the underlying underpayment or deficiency is attributable to an executor's negligence, disregard of the rules or regulations (including careless, reckless, or intentional disregard of rules or regulations) as defined in § 1.6662–3(b)(2), or fraud with intent to evade tax, the interest expense is not an expense actually and necessarily incurred in the administration of the estate. Accordingly, the Treasury Department and the IRS have determined that, when interest accrues on any unpaid tax or penalty and the interest expense is attributable to an executor's negligence, disregard of the rules or regulations, or fraud with intent to evade tax, the interest expense is neither actually and necessarily incurred in the administration of the estate nor essential to the proper settlement of the estate. Further, the Treasury Department and the IRS have determined that the rationale underlying this determination applies to all non-section 6166 interest, whether the interest accrues in connection with a deferral, underpayment, or deficiency.

The proposed regulations amend the regulations under section 2053 to confirm that section 6166 interest on estate tax deferred under section 6166, including interest accruing on an installment under section 6166 during the period of an extension of time for payment under section 6161(a)(2)(B), is not a deductible administration expense under section 2053. The proposed regulations also provide that non-section 6166 interest that accrues on or after the decedent's date of death on any unpaid tax or penalties may be deductible to the extent permitted by §§ 20.2053–1 and 20.2053–3(a). The proposed regulations further provide that non-section 6166 interest on estate tax deferred under section 6161 or section 6163 is actually and necessarily incurred in the administration of the estate because the grant of the extension was based on a demonstrated need to defer payment. Finally, the proposed regulations provide that, in general, non-section 6166 interest accruing post-death on any unpaid tax or penalties in connection with an underpayment of tax or a deficiency is actually and necessarily incurred in the administration of the estate. However, the proposed regulations provide that, notwithstanding these rules, non-section 6166 interest accruing on unpaid tax and penalties on and after the decedent's date of death, whether in connection with a deferral, underpayment, or deficiency, is not actually and necessarily incurred in the administration of the estate and is not deductible to the extent the interest expense is attributable to an executor's negligence, disregard of applicable rules or regulations (including careless, reckless, or intentional disregard of rules or regulations) as defined in § 1.6662–3(b)(2), or fraud with intent to evade tax. Interest expense is attributable to an executor's negligence, disregard of applicable rules or regulations, or fraud with intent to evade tax to the extent that the underlying underpayment, deficiency, or penalty is attributable to such conduct by the executor. Similarly, even when the underlying underpayment, deficiency, or penalty is not attributable to such conduct by the executor, interest expense is attributable to an executor's negligence, disregard of applicable rules or regulations, or fraud with intent to evade tax to the extent the subsequent

accrual of interest is attributable to such conduct by the executor.

The rules in the proposed regulations pertaining to whether non-section 6166 interest satisfies the requirement in § 20.2053–3(a) supplant the rule reflected in Rev. Rul. 79–252, 1979–2 C.B. 333, and in the second holding of Rev. Rul. 81–154, 1981–1 C.B. 470. (*See* § 601.601(d)(2)(ii)(*b*).) Together, these two holdings create an implicit presumption that interest accruing on any unpaid portion of tax or penalties in all cases satisfies the requirements for a deductible administration expense, which is inconsistent with the requirement in § 20.2053–3(a) that the expense be actually and necessarily incurred in the administration of the estate.

2. Interest Accruing on Certain Loan Obligations Incurred by an Estate

The same requirements that apply for deductible interest accruing on unpaid tax and penalties also apply for deductible interest accruing on loan obligations incurred by an estate. Interest accruing on a loan obligation incurred by an estate satisfies the ''bona fide'' requirement in § 20.2053–1(b)(2) when both the interest expense and the loan underlying the interest expense are bona fide in nature and do not constitute a transfer that is essentially donative in character. Such interest satisfies the ''actually and necessarily incurred'' requirement in § 20.2053–3(a) when the loan on which the interest expense accrues and its terms are necessary to the administration of the decedent's estate and are essential to the proper settlement of the decedent's estate.

Among the reasons an estate might enter into a loan arrangement is to facilitate the payment of the estate's taxes and other liabilities or the administration of the estate. Some estates face genuine liquidity issues that make it necessary to find a means to satisfy their liabilities, and incurring a loan obligation on which interest accrues may be the only or best way to obtain the necessary liquid funds. However, if illiquidity has been created intentionally (whether in the estate planning, or by the estate with knowledge or reason to know of the estate tax liability) prior to the creation of the loan obligation to pay estate expenses and liabilities, the underlying loan may be bona fide in nature but most likely will not be found to be actually and necessarily incurred in the administration of the estate.

The issue of the deductibility of interest expense accruing on a loan obligation incurred by an estate has been litigated often, with varying results. *See, e.g., Estate of Black* v. *Commissioner,* 133 T.C. 340 (2009); *Estate of Graegin* v. *Commissioner,* T.C. Memo. 1988–477. In order to provide guidance on the deductibility of interest accruing on a loan obligation entered into by the decedent's estate to facilitate the payment of the estate's taxes and other liabilities or the administration of the estate, the Treasury Department and the IRS propose to amend the regulations under section 2053. The proposed regulations provide that interest expense is deductible only if: (i) the interest accrues pursuant to an instrument or contractual arrangement that constitutes indebtedness under applicable income tax regulations and general principles of Federal tax law; (ii) both the interest expense and the loan on which interest expense accrues satisfy the requirement of § 20.2053–1(b)(2) that they are bona fide in nature; and (iii) the loan on which interest accrues and the loan's terms are actually and necessarily incurred in the administration of the decedent's estate and are essential to the proper settlement of the decedent's estate (within the meaning of § 20.2053–3(a)).

Finally, the proposed regulations include a nonexclusive list of factors to consider in determining whether interest expense payable pursuant to such a loan obligation of an estate satisfies the requirements of §§ 20.2053–1(b)(2) and 20.2053–3(a). In general, the factors suggest that interest accruing on a loan obligation may satisfy these requirements when the loan and its underlying terms are reasonable and comparable to an arms-length loan transaction and correspond to the estate's ability to satisfy the loan, and the loan obligation is entered into by the executor with a lender who is not a substantial beneficiary of the decedent's estate (or an entity controlled by such a beneficiary) at a time when there is no viable alternative to obtain the necessary liquid funds to satisfy estate liabilities. In addition to providing guidance on when interest accruing on a loan obligation may satisfy the requirements of §§ 20.2053–1(b)(2) and 20.2053–3(a), the list of factors may suggest when the opposite is true and interest accruing on a loan obligation does not satisfy these requirements. For instance, if, taken in their entirety, the facts and circumstances indicate that either the need for the loan or any of the loan terms are contrived to generate, or increase the amount of, a deduction for the interest expense, the interest is not deductible. Thus, if the lender is a primary beneficiary of the estate (or an entity controlled by such beneficiary) who may have liability for payment of the estate tax or whose share of the estate may bear the burden of estate taxes and other liabilities, the facts indicate the loan is not necessarily incurred in the administration of the estate and, therefore, indicate that any interest accruing on the loan is not necessarily incurred in the administration of the estate. Further, if the loan obligation carries an extended loan term with a single balloon payment that does not correspond with the estate's ability to satisfy the loan, the facts indicate that the interest accruing on the loan is not necessarily incurred in the administration of the estate.

IV. Substantiation Requirements for Valuations Performed Pursuant to § 20.2053–4(b) and (c)

A. Issue Background

Section 20.2053–4(b) and (c) provides exceptions to the general rule in § 20.2053–4(a) that an estate may deduct only amounts that actually are paid by the estate in satisfaction of a claim. Section 20.2053–4(b) generally allows a deduction for the value of claims and counterclaims in a related matter, and § 20.2053–4(c) allows a deduction for the value of unpaid claims totaling not more than $500,000. In each case, certain requirements must be satisfied to enable the estate to use these exceptions.

One such requirement is that the value of a claim against the estate that may be deducted under either § 20.2053–4(b) or (c) must be determined from a ''qualified appraisal'' performed by a ''qualified appraiser'' within the meaning of section 170 and the regulations thereunder. The Treasury Department and the IRS have reconsidered this requirement. The definition of ''qualified appraiser'' and ''qualified appraisal'' in the regulations under section 170 were drafted in the context of appraising an asset being donated, and not a liability such as a claim against an estate. Certain of the elements of a qualified appraisal, including references to the ''date of contribution,'' and the requirements necessary to meet the definition of a ''qualified appraiser,'' do not apply in the context of valuing a claim against an estate for purposes of determining the value to be deducted from the gross estate under section 2053.

The Treasury Department and the IRS have determined that the rule in § 20.2053–4(b) and (c) should be amended to remove the requirement that the value be determined by a ''qualified appraisal'' performed by a

''qualified appraiser'' within the meaning of section 170 and the regulations thereunder. Instead, the Treasury Department and the IRS propose to amend the regulations under section 2053 to provide revised rules for valuing claims for purposes of § 20.2053–4(b) and (c).

B. Explanation of Provision

The Treasury Department and the IRS propose to amend the regulations under section 2053 to remove the requirement in § 20.2053–4(b)(1)(iv) and (c)(1)(iv) that valuations of the claims deductible under § 20.2053–4(b) and (c) must be supported by a ''qualified appraisal'' performed by a ''qualified appraiser.'' For purposes of determining the allowable deduction under § 20.2053–4(b) and (c), these proposed regulations instead provide new requirements intended to facilitate the appropriate valuation of these claims.

Specifically, to determine the current value of a claim deductible under § 20.2053–4(b) or (c), the proposed regulations require a written appraisal that adequately reflects the current value of the claim when the Form 706 is being completed. The current value of the claim should take into account post-death events occurring prior to the time a deduction is claimed as well as those events reasonably anticipated to occur. In addition, the proposed regulations require the written appraisal to consider all relevant facts and elements of value that are known or that can be reasonably anticipated at the time of the appraisal. The written appraisal must be prepared, signed, and dated by a person who is qualified to appraise the claim being valued, but who is not (i) a family member of the decedent, a related entity as to the decedent, or a beneficiary of the decedent's estate or revocable trust (as those terms are defined in § 20.2053–1(b)(2)(iii)), (ii) a family member of a beneficiary or a related entity as to a beneficiary (as those terms would be defined in § 20.2053–1(b)(2)(iii) if references therein to the decedent were replaced with a reference to such beneficiary, and without the limitations based on the decedent's date of death), or (iii) an employee or other owner of any of them. The appraisal also must include a statement describing the basis for the person's qualification to appraise the claim being valued.

V. Deductibility of Amounts Paid Pursuant to Decedent's Personal Guarantee

A. Issue Background

A commenter responding to the 2007 Proposed Regulations suggested that the final regulations confirm that payments made pursuant to a decedent's personal guarantee existing at the decedent's death are deductible in the same manner as payments made in satisfaction of any other deductible claim against a decedent's estate.

For payments made pursuant to a decedent's obligation as a guarantor of indebtedness to be deductible, the claim must represent a personal obligation of the decedent existing at the time of the decedent's death, and the claim must be enforceable against the decedent's estate. *See* § 20.2053–4(a)(1). However, not all enforceable debts are deductible under section 2053. A claim founded upon a decedent's guarantee is considered a claim founded upon a promise or agreement. Accordingly, the deduction for such a claim is limited to the extent that the guarantee was contracted bona fide and in exchange ''for an adequate and full consideration in money or money's worth.'' *See* section 2053(c)(1)(A) and § 20.2053–4(d)(5). For a claim founded upon a decedent's guarantee to satisfy the ''adequate and full consideration in money or money's worth'' requirement and, therefore, be deductible under section 2053, the decedent must have received a benefit reducible to money value in exchange for the decedent's guarantee. *See United States* v. *Stapf,* 375 U.S. 118, 131 (1963) (''Absent such an . . . augmentation of the estate, a testator could disguise transfers as payments in settlement of debts and claims and thus obtain deductions for transmitting gifts.''); *Commissioner* v. *Wemyss,* 324 U.S. 303 (1945) (construing the requirement of ''adequate and full consideration in money or money's worth'' in the gift tax context to require a benefit to the donor reducible to money value ''to relieve a transfer by him from being a gift.''); *Estate of Theis* v. *Commissioner,* 81 T.C. 741, 745, 748 (1983) (noting the amounts at issue must have been contracted bona fide and for full and adequate consideration), *aff'd* 770 F.2d 981 (11th Cir. 1985).

Guarantor agreements often are required in the context of a loan to the guarantor's closely-held business. In these cases, the guarantor may be motivated to enter into the guarantee agreement to preserve the value of the guarantor's interest in the business. The Treasury Department and the IRS have determined that it is appropriate to provide guidance on whether, for purposes of section 2053, a guarantor agreement is contracted for an adequate and full consideration in money or money's worth in such a situation for purposes of section 2053.

When payments pursuant to a decedent's guarantee satisfy the requirements for a deductible claim, the amount deductible is limited to the portion of the total claim due from and actually paid by the estate, but reduced by the amount recovered, or the amount that could have been recovered, from another party, insurance, or otherwise. *See* §§ 20.2053–1(d)(1) and (3) and 20.2053–4(d)(3). Further, to avoid the double-counting of a debt that occurs when the debt both is taken into account in computing the gross estate and is taken as a section 2053 deduction, payments made pursuant to the decedent's guarantee are deductible only to the extent that the debt for which the guarantee is given has not been taken into account in computing the value of an asset includible in the decedent's gross estate.

A regulatory provision specifically addressing the deductibility of claims founded upon a decedent's guarantee will assist taxpayers in understanding and meeting their tax responsibilities and will result in consistent treatment for similarly situated taxpayers.

B. Explanation of Provision

The proposed regulations provide that a claim founded upon the decedent's agreement to personally guarantee a debt of another is a claim founded on a promise and, accordingly, must satisfy the applicable requirements in section 2053(c)(1)(A) and § 20.2053–4(d)(5). Specifically, the guarantee must have been bona fide and in exchange for adequate and full consideration in money or money's worth. The proposed regulations confirm that the bona fide nature of a claim related to the guarantee of a debt of a family member, a related entity, or a beneficiary will be determined with reference to § 20.2053–1(b)(2)(ii). The proposed regulations provide a bright line rule that a decedent's agreement to guarantee a bona fide debt of an entity in which the decedent had control (within the meaning of section 2701(b)(2)) at the time of the guarantee satisfies the requirement that the agreement be in exchange for adequate and full consideration in money or money's worth. Alternatively, the proposed regulations provide that this requirement also is satisfied if, at the time the guarantee is given, the maximum liability of the decedent under the guarantee did not exceed the fair market value of the decedent's interest in the entity. Finally, the proposed regulations provide that the estate's right of contribution or reimbursement will reduce the amount

deductible in accordance with § 20.2053–1(d)(3).

Proposed Applicability Date

The regulations are proposed to apply to the estate of each decedent dying on or after the date of publication in the **Federal Register** of a Treasury decision adopting these rules as final regulations.

Effect on Other Documents

Rev. Rul. 79–252 (1979–2 C.B. 333) states that interest on a Federal estate tax deficiency is a necessary administration expense under section 2053(a)(2) and is deductible to the extent allowable under local law. Rev. Rul. 81–154 (1981–1 C.B. 470) states, in the second holding, that interest incurred because of a late payment of tax is deductible under section 2053(a)(2) to the extent it is allowable under local law. Rev. Rul. 79–252 will be obsoleted and Rev. Rul. 81–154 will be modified, effective as of the date that a Treasury decision adopting these rules as final regulations is published in the **Federal Register**.

Statement of Availability of IRS Documents

IRS revenue procedures, revenue rulings, notices, and other guidance cited in this document are published in the Internal Revenue Bulletin (or Cumulative Bulletin) and are available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at *https://www.irs.gov.*

Special Analyses

Regulatory Planning and Review

This regulation is not subject to review under section 6(b) of Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Treasury Department and the Office of Management and Budget regarding review of tax regulations. Therefore, a regulatory impact assessment is not required.

Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that these regulations primarily affect estates of a decedent which generally are not small entities under the Act. Accordingly, these regulations are not expected to have a significant economic impact on a substantial number of small entities, and a regulatory flexibility analysis is not required.

Pursuant to section 7805(f) of the Code, these proposed regulations will be submitted to the Chief Counsel for the Office of Advocacy of the Small Business Administration for comment on their impact on small businesses.

Paperwork Reduction Act

The collections of information contained in this notice of proposed rulemaking have been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), under Form 706, *United States Estate (and Generation-Skipping Transfer) Tax Return,* and assigned control number 1545–0015. Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, and to Clearance Officer, SE:CAR:MP:T:T:SP, Washington, DC 20224. Comments on the collection of information should be received by August 29, 2022. Comments are specifically requested concerning:

Whether the proposed collections of information are necessary for the proper performance of the functions of the IRS, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information;

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collections of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs of operation, maintenance, and purchase of services to provide information.

The collections of information in these proposed regulations are in proposed §§ 20.2053–1(d)(6)(iv) and 20.2053–4(b)(1)(iv) and (c)(1)(iv). The information requested in § 20.2053–1(d)(6)(iv) is necessary in order to evaluate whether an estate is entitled to a deduction in the amount claimed on Form 706. The collection of information is mandatory to obtain a benefit. The information requested in § 20.2053–4(b)(1)(iv) and (c)(1)(iv) is necessary in order to evaluate whether an estate is entitled to a deduction claimed on Form 706 and, if so, the amount of the deduction. The collection of information is mandatory to obtain a benefit. The likely respondents are estates of decedents seeking to deduct on Form 706 funeral expenses, administration expenses, and/or certain claims against the estate under section 2053.

Estimated total annual reporting burden: 23,661 hours.

Estimated average annual burden per respondent: 3 hours.

Estimated number of respondents: 7,887.

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 control number assigned by the Office of Management and Budget.

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.

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a state, local, or tribal government, in the aggregate, or by the private sector, of $100 million (updated annually for inflation). This proposed rule does not include any Federal mandate that may result in expenditures by state, local, or tribal governments, or by the private sector in excess of that threshold.

Executive Order 13132: Federalism

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

Drafting Information

The principal authors of these regulations are Karlene Lesho and Melissa Liquerman, Office of the Associate Chief Counsel (Passthroughs and Special Industries). However, other personnel from the Treasury Department and the IRS participated in their development.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in this preamble under the **ADDRESSES** section. The Treasury Department and the IRS request comments on all aspects of the proposed regulations.

Any electronic comments submitted, and to the extent practicable, any paper comments submitted, will be made available at *www.regulations.gov* or upon request.

A public hearing is being held by teleconference on October 12, 2022, at 10:00 a.m. EST unless no outlines are received by September 26, 2022.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to comment by telephone at the hearing must submit electronic or written comments and an outline of the topics to be discussed and the time to be devoted to each topic by September 26, 2022 as prescribed in the preamble under the **ADDRESSES** section. A period of ten minutes will be allotted to each person for making comments (although this rule may be waived in unusual circumstances or for good cause shown). After the deadline for receiving outlines has passed, the IRS will prepare an agenda containing the schedule of speakers. Copies of the agenda will be made available at *www.regulations.gov,* search IRS and REG–130975–08. Copies of the agenda will also be available by emailing a request to *publichearings@irs.gov.* Please put ''REG–130975–08 Agenda Request'' in the subject line of the email.

Announcement 2020–4, 2020–17 IRB 667 (April 20, 2020), provides that until further notice, public hearings conducted by the IRS will be held telephonically. Any telephonic hearing will be made accessible to people with disabilities.

List of Subjects in 26 CFR Part 20

Estate taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, the IRS proposes to amend 26 CFR part 20 as follows:

PART 20—ESTATE TAX; ESTATES OF DECEDENTS DYING AFTER AUGUST 16, 1954

■ **Paragraph 1.** The authority citation for part 20 continues to read in part as follows:

Authority: 26 U.S.C. 7805.

* * * * *

■ **Par. 2.** Section 20.2053–1 is amended by:

■ 1. Adding paragraph (d)(6).

■ 2. Revising the introductory text of paragraph (d)(7).

■ 3. In paragraph (d)(7), *Examples 1* through *3* are designated as paragraphs (d)(7)(i) through (iii), respectively.

■ 4. In newly designated paragraphs (d)(7)(i) and (ii):

■ i. Removing ''*ascertainable,*'' and adding ''*ascertainable.*'' in its place.

■ ii. Adding a sentence to the end of the paragraphs.

■ 5. In newly designated paragraph (d)(7)(iii):

■ i. Removing ''*deduction,*'' and ''*Example 2*'' and adding ''*deduction.*'' and ''paragraph (d)(7)(ii) of this section (*Example 2*)'' in their places, respectively.

■ ii. Revising the last sentence of the paragraph.

■ 6. Adding paragraphs (d)(7)(iv) through (vi).

■ 7. Revising paragraph (f).

The additions and revisions read as follows:

§ 20.2053–1 Deductions for expenses, indebtedness, and taxes; in general.

* * * * *

(d) * * *

(6) *Limitation on amount deductible*—(i) *Claims and expenses paid after the grace period*—(A) *Definitions.* The following definitions apply for purposes of this paragraph (d):

(*1*) *Grace period.* The *grace period* is the period beginning on the date of the decedent's death and extending through the third anniversary of that date.

(*2*) *Post-grace-period payment.* A *post-grace-period payment* is the amount of a claim or expense described in paragraph (a) of this section not paid or to be paid before the end of the grace period.

(B) *General rule.* To the extent that a post-grace-period payment otherwise meets the requirements for deductibility of a claim or expense under section 2053 and the regulations in this part thereunder, the amount deductible under section 2053 is limited to the present value, as of the decedent's date of death, of that amount. The present value of each post-grace-period payment is calculated by discounting it from the payment date or expected date of payment to the decedent's date of death. The applicable discount rate is the applicable Federal rate determined under section 1274(d) for the month in which the decedent's death occurs, compounded annually. The length of time from the decedent's date of death to the date of payment or expected date of payment will determine whether the Federal rate applicable to that payment is the Federal mid-term rate or the Federal long-term rate. The Internal Revenue Service publishes the applicable Federal rates for each month in the Internal Revenue Bulletin (*see* § 601.601(d)(2)(ii) of this chapter). Any reasonable assumptions and methodology in regard to time period measurements may be used to calculate, in accordance with paragraph (d)(6)(ii) of this section, the present value of the post-grace-period payment(s).

(ii) *Calculating present value of amounts paid or payable*—(A) *Single post-grace-period payment.* The amount deductible under section 2053 for a single post-grace-period payment is computed by calculating the present value of such payment as follows:

$$\text{Amount of future payment} \times [1 \div (1 + i)]^{t}$$

Where:

t is the amount of time (expressed in years and fractions of years) from the day after the decedent's date of death to the payment date or expected date of payment; and

i is the applicable discount rate.

(B) *Multiple post-grace-period payments.* The amount deductible under section 2053 for multiple post-grace-period payments is computed by calculating the present value of each such payment using the formula in paragraph (d)(6)(ii)(A) of this section; the sum of the discounted amounts of the post-grace-period payments is the amount that is deductible for such payments.

(C) *Multiple payment dates occurring during and after the grace period.* A claim or expense described in paragraph (a) of this section may have at least one payment date or expected date of payment during the grace period and at least one payment date or expected date of payment after the grace period. For such a claim or expense, the amount deductible under section 2053 is computed by calculating the present value of each separate post-grace-period payment using the formula in paragraph (d)(6)(ii)(A) of this section, and adding the total of these discounted amounts to any amount of the claim or expense having a payment date or expected date of payment during the grace period. Any amount having a payment date or expected date of payment during the grace period is not discounted in arriving at the amount deductible.

(iii) *Discounting when actual date of payment is unknown.* With regard to a post-grace-period payment that may be deducted in advance of payment under paragraph (d)(4) of this section or § 20.2053–4(b) or (c), the amount

deductible must be determined by computing the present value of the amount of that post-grace-period payment as if that amount will be paid on the expected date of payment. The expected date of payment in settlement or satisfaction of a claim or expense must be determined using all information reasonably available to the taxpayer to make a fair and reasonable estimate of the expected date or dates of payment. For amounts deductible under § 20.2053–4(b) or (c), the expected date or dates of payment must be identified in a written appraisal document of a person that is qualified by knowledge and experience to appraise the claim being valued. *See* § 20.2053–4(b)(1)(iv) and (c)(1)(iv). However, the computation of present value is subject to adjustment if, within the period described in paragraph (d)(2) of this section, the actual date or dates of payment become known and differ from the estimated date or dates of payment. *See* paragraph (d)(6)(vi) of this section.

(iv) *Statement supporting present value computation required.* A deduction under section 2053 for a claim or expense that is required to be discounted to present value under paragraph (d)(6)(i) of this section must be supported by a statement to be filed with the Form 706 showing the computation of the present value of that item, including, if applicable, the basis for the determination of the expected date(s) of payment.

(v) *Ordering rule.* In computing the amount deductible for a claim or expense under paragraph (d) of this section, the amount deductible for a claim or expense (otherwise determined under paragraphs (d)(1) through (4) of this section) is discounted to present value under paragraph (d)(6) of this section before applying the limits in § 20.2053–4(b)(2) and (c).

(vi) *Effect of post-death events.* If a deduction is claimed for the present value of a post-grace-period payment, the claimed deduction is subject to adjustment to reflect any post-death events affecting the amount of such post-grace-period payment and any change in the expected or actual date of payment. *See* paragraph (d)(2) of this section for the period during which post-death events are taken into account.

(vii) *Exceptions.* The rule in paragraph (d)(6)(i) of this section does not apply to unpaid principal of mortgages and other indebtedness deductible under § 20.2053–7.

(7) *Examples.* Assume that the amounts described in section 2053(a) are payable out of property subject to claims and are allowable by the law of the jurisdiction governing the administration of the estate, whether the applicable jurisdiction is within or outside of the United States. Assume that, unless otherwise provided, the claims against the estate are not deductible under § 20.2053–4(b) or (c) and all amounts are paid during the grace period. The following examples illustrate the application of this paragraph (d):

(i) * * * However, any amounts that will not be paid on or before the third anniversary of the date of D's death (that is, are not paid during the grace period) are subject to the present value limitation in paragraph (d)(6) of this section.

(ii) * * * If the amount of the claim will not be paid on or before the third anniversary of the date of D's death (that is, the amount is not paid during the grace period), the amount deductible is subject to the present value limitation in paragraph (d)(6) of this section.

(iii) * * * At that time, a deduction will be allowed for the amount that is either paid or meets the requirements of paragraph (d)(4) of this section for deducting certain ascertainable amounts, subject to the present value limitation in paragraph (d)(6) of this section, if applicable.

(iv) *Example 4: Discounting amount paid more than three years after decedent's date of death.* The facts are the same as in paragraph (d)(7)(ii) of this section (*Example 2*) except that E files a timely protective claim for refund in accordance with paragraph (d)(5) of this section to preserve the estate's right to claim a refund, a final judgment in the amount of $100x is entered against and paid by the estate precisely five years after D's date of death, and the applicable Federal (mid-term) rate determined under section 1274(d) for the month in which D's date of death occurs, compounded annually, is 2.00%. Within a reasonable period of time after the final judgment is entered, E notifies the Commissioner that the contingency has been resolved. E may claim a deduction for the present value of the amount paid in satisfaction of the claim as of D's date of death. Under the facts in this paragraph (d)(7)(iv), the present value of the amount paid in five years equals $100x/(1 + .0200)^5 or $100x/1.104081 or $90.57x.

(v) *Example 5: Discounting amount to be paid when actual date of payment not known.* The facts are the same as in paragraph (d)(7)(ii) of this section (*Example 2*) except that the claim is deductible under § 20.2053–4(c) because all amounts deducted by the estate under that paragraph do not exceed $500,000. E obtains a written appraisal document meeting the requirements of § 20.2053–4(c)(iv) and reasonably determines that the future value of the claim is $300,000 (that is, before discounting the claim to its present value). E determines, after considering all available information and making reasonable assumptions, that the expected date of payment of the claim is Date X, which is reflected in the appraisal. Date X is a date after the third anniversary of D's date of death. E may claim a deduction for the present value of the claim as of D's date of death, determined by discounting $300,000 for the period from the date of death to Date X, using the applicable Federal rate determined under section 1274(d) for the month in which D's death occurs, compounded annually.

(vi) *Example 6: Discounting amount to be paid for series of payments payable over a period that does not end on or before the third anniversary of the decedent's death.* Pursuant to the terms of a divorce and separation agreement entered on June 1 of Year 1, Decedent (D) is obligated to make annual payments of $100x to Claimant (C) on September 1 of year 1 and each September 1st thereafter until D has made a total of 10 such payments. D dies on December 1 of Year 5 after having made the first five annual payments required under the agreement. The applicable Federal (mid-term) rate determined under section 1274(d) for the month in which D's death occurs, compounded annually, is 2.00%. The executor of D's estate (E) may claim a deduction with respect to C's claim on D's Form 706 under the special rule contained in paragraph (d)(4) of this section because the deductible amount can be ascertained with reasonable certainty. E computes the discounted deductible amount of the claim by adding the undiscounted amount of the three payments that will be made before the third anniversary of D's death ($300x) to the discounted amounts of the two payments that will be made after the third anniversary of D's death. Accordingly, the amount deductible for the claim equals $483.866x ($300x + $92.843x + $91.023x). The individual calculations for the present values of the payments in the last two years of the payment obligation are shown in table 1 to this paragraph (d)(7)(vi).

TABLE 1 TO PARAGRAPH (d)(7)(vi)

	(1)	(2)	(3)	(4)	(5)
	t	1 + i	1/(1 + i)	$[1/(1 + i)]^t$	$[1/(1 + i)]^t \times 100x$
Year 9	3.75	1.0200	0.980392	0.928430	92.843x
Year 10	4.75	1.0200	0.980392	0.910226	91.023x

* * * * *

(f) *Applicability date.* The rules of this section apply to the estates of decedents dying on or after [date of publication of the final rule in the **Federal Register**].

■ **Par. 3.** Section 20.2053–3 is amended by:

■ 1. Redesignating paragraphs (d) and (e) as paragraphs (e) and (f), respectively.

■ 2. Adding a new paragraph (d).

■ 3. Revising newly redesignated paragraph (f).

The addition and revision read as follows:

§ 20.2053–3 Deduction for expenses of administering estate.

* * * * *

(d) *Interest expense incurred in administering the estate*—(1) *Interest payable under section 6601 on unpaid tax*—(i) *Section 6166 interest.* As used in paragraph (d)(1) of this section, the phrase ''section 6166 interest'' means interest payable under section 6601 on unpaid estate tax deferred under section 6166. This includes interest accruing on an installment or other payment under section 6166 during the period of an extension of time for making that payment under section 6161(a)(2)(B). Section 6166 interest is not deductible pursuant to section 2053(c)(1)(D).

(ii) *Non-section 6166 interest.* As used in paragraph (d)(1) of this section, the phrase ''non-section 6166 interest'' means interest payable under section 6601 or under state or local law other than section 6166 interest. Non-section 6166 interest that accrues on or after the decedent's date of death on any unpaid tax or penalties may be deductible to the extent permitted by § 20.2053–1 and this section. For purposes of paragraph (d)(1) of this section, penalties include any unpaid additions to tax, additional taxes, and penalties. When non-section 6166 interest accrues on unpaid estate tax deferred under section 6161 or section 6163, the interest expense is actually and necessarily incurred in the administration of the estate for purposes of paragraph (a) of this section because the extension was based on a demonstrated need to defer payment. When non-section 6166 interest accrues on and after the date of a decedent's death on any unpaid tax or penalties in connection with an underpayment of tax or a deficiency, the interest expense generally is actually and necessarily incurred in the administration of the estate for purposes of paragraph (a) of this section.

(iii) *Exception.* Notwithstanding paragraph (d)(1)(ii) of this section, non-section 6166 interest accruing on unpaid tax and penalties on and after the decedent's date of death, whether in connection with a deferral, underpayment, or deficiency, is not actually and necessarily incurred in the administration of the estate for purposes of paragraph (a) of this section and is not deductible to the extent the interest expense is attributable to an executor's negligence, disregard of applicable rules or regulations (including careless, reckless, or intentional disregard of rules or regulations) as defined in § 1.6662–3(b)(2) of this chapter, or fraud with intent to evade tax. Interest expense is attributable to an executor's negligence, disregard of applicable rules or regulations, or fraud with intent to evade tax to the extent that the underlying deferral, underpayment, or deficiency, is attributable to such conduct by the executor. Similarly, even when the underlying deferral, underpayment, or deficiency is not attributable to such conduct by the executor, the interest expense is attributable to an executor's negligence, disregard of the rules or regulations, or fraud with intent to evade tax to the extent the subsequent accrual of interest is attributable to such conduct by the executor.

(iv) *Examples.* The following examples illustrate the application of this paragraph (d)(1). In each example, the decedent (D) dies on October 1, Year 1, and the estate tax return is due July 1 of the following calendar year, Year 2. In each example, except as expressly stated, there is no negligence, disregard of applicable rules or regulations, or fraud on the part of the executor.

(A) *Example 1.* On July 1, Year 2, the executor of D's estate (E) timely files the estate tax return based on values determined in good faith and pays $500,000, which is the estate tax shown on the return. Upon examination, the Internal Revenue Service (IRS) makes an adjustment to the value of an asset includible in the gross estate, resulting in a $25,000 increase in estate tax due. E initially contests the adjustment, but eventually agrees to the assessment of the deficiency in the amount of $25,000. Interest on the deficiency is payable under section 6601 in the amount of $X. E makes a payment in satisfaction of the assessed deficiency and interest. For purposes of paragraph (a) of this section, the interest expense in the amount of $X is considered actually and necessarily incurred in the administration of D's estate, and its deduction reduces the amount of the deficiency.

(B) *Example 2.* The executor of D's estate (E) files the estate tax return and pays the estate tax shown on the return ($500,000) on July 1 of Year 3, one year after the due date. On August 1, Year 3, the IRS assesses interest on the unpaid tax under section 6601 in the amount of $X, assesses late filing and late payment penalties in accordance with section 6651 in the amount of $Y, and issues a notice and demand for payment of $X and $Y. On August 1, Year 4, E makes payment to the IRS of $Z, which is the total amount due for $X and $Y, as well as interest that accrued on these amounts from August 1, Year 3, to August 1, Year 4, payable under section 6601. The facts establish that E's failure to timely file the return and timely pay the tax and failure to pay the assessed interest and penalties within the period provided in the notice and demand is a result of E's disregard of the rules for filing the return and paying the tax and any assessed penalties. Under the facts in this paragraph (d)(1)(iv)(B), neither the interest payable under section 6601 that accrued on the unpaid tax before notice and demand nor the interest that accrued on the unpaid tax and penalties after notice and demand is an expense that is actually and necessarily incurred in the administration of D's estate for purposes of paragraph (a) of this section.

(C) *Example 3.* Prior to D's death, the IRS had assessed an income tax deficiency against D for the 2009 tax period in the amount of $75,000, and penalties in the amount of $X. The assessed tax and penalties remained unpaid on D's date of death. On July 1, Year 2, the executor of D's estate (E) timely files the estate tax return and timely pays the estate tax shown on the

return to be due. On the same date, E also pays all claims against and liabilities of the estate, except for the assessed income tax deficiency and penalties for the 2009 tax period. Despite E's awareness that the estate had sufficient liquidity and funds to satisfy all estate liabilities, including the 2009 income tax deficiency and penalties, E does not pay the assessed income tax deficiency, penalties, and accrued interest until July 1, Year 4. E's failure to pay the assessed income tax deficiency and penalties for the 2009 tax period is a result of E's disregard of applicable rules or regulations. Even though the underlying income tax deficiency is not attributable to E's negligence, disregard of applicable rules, or fraud with intent to evade tax, the interest that accrued after July 1, Year 2, on the assessed deficiency and penalties is attributable to E's disregard of applicable rules or regulations. Accordingly, the post-July 1, Year 2, interest is not an expense that is actually and necessarily incurred in the administration of D's estate.

(2) *Interest expense on certain loan obligations of the estate.* Interest on a loan entered into by the estate to facilitate the payment of the estate's tax and other liabilities or the administration of the estate may be deductible depending on all the facts and circumstances. To be a deductible administration expense, interest expense must arise from an instrument or contractual arrangement that constitutes indebtedness under applicable income tax regulations and general principles of Federal tax law. In addition, the interest expense and the loan to which interest expense relates must satisfy the requirement of § 20.2053–1(b)(2) that they are bona fide in nature based on all the facts and circumstances. Further, both the loan to which the interest expense relates and the loan terms must be actually and necessarily incurred in the administration of the decedent's estate and must be essential to the proper settlement of the decedent's estate. *See* paragraph (a) of this section. If the facts and circumstances establish that the interest expense arises from an instrument or contractual arrangement that constitutes indebtedness under general principles of Federal tax law, factors that collectively may support a finding that the interest expense also satisfies the additional requirements under § 20.2053–1(b)(2) and paragraph (a) of this section include, but are not limited to, the following:

(i) The interest rate on and the terms of the underlying loan (whether between related or unrelated parties), including any prepayment penalty, are reasonable given all the facts and circumstances and comparable to an arms-length loan transaction;

(ii) The underlying loan is entered into by an executor of the decedent's estate acting in the capacity of executor or, if no executor is appointed and acting, the person accountable for satisfying the liabilities of the estate;

(iii) The lender properly includes amounts of paid and/or accrued interest (including original issue discount as determined under sections 1271 through 1275 and the regulations in this part under those sections, such as original issue discount attributable to stated interest that is treated as part of the stated redemption price at maturity because it is not payable at least annually) in gross income for Federal income tax purposes, particularly if the lender is a family member of the decedent, a related entity, or a beneficiary of the decedent's estate or trust (as defined in § 20.2053–1(b)(2)(iii));

(iv) The loan proceeds are used to satisfy estate liabilities that are essential to the proper settlement of the estate, including, but not limited to, the Federal estate tax liability;

(v) The loan term and payment schedule correspond to the estate's anticipated ability to make the payments under, and to satisfy, the loan, and the loan term does not extend beyond what is reasonably necessary;

(vi) The only practical alternatives to the loan are the sale of estate assets at prices that are significantly below-market, the forced liquidation of an entity that conducts an active trade or business, or some similar financially undesirable course of action;

(vii) The underlying loan is entered into when the estate's liquid assets are insufficient to satisfy estate liabilities, the estate does not have control (within the meaning of section 2701(b)(2)) of an entity that has liquid assets sufficient to satisfy estate liabilities, the estate has no power to direct or compel an entity in which it has an interest to sell liquid assets to enable the estate to satisfy its liabilities, and the estate's assets are expected to generate sufficient cash flow or liquidity to make the payments required under the loan;

(viii) The estate's illiquidity does not occur after the decedent's death as a result of the decedent's testamentary estate plan to create illiquidity; similarly, the illiquidity does not occur post-death as a deliberate result of the action or inaction of the executor who then had both knowledge or reason to know of the estate tax liability and a reasonable alternative to that action or inaction that could have avoided or mitigated the illiquidity;

(ix) The lender is not a beneficiary of a substantial portion of the value of the estate, and is not an entity over which such a beneficiary has control (within the meaning of section 2701(b)(2)) or the right to compel or direct the making of the loan;

(x) The lender or lenders are not beneficiaries of the estate whose individual share of liability under the loan is substantially similar to his or her share of the estate; and

(xi) The decedent's estate has no right of recovery of estate tax against, or of contribution from, the person loaning the funds.

* * * * *

(f) *Applicability date.* The rules of this section apply to the estates of decedents dying on or after [date of publication of the final rule in the **Federal Register**].

■ **Par. 4.** Section 20.2053–4 is amended by:

■ 1. Revising paragraphs (b)(1)(iv), (b)(2), and (c)(1)(iv) and (v), the second sentence of paragraph (c)(3), paragraph (d)(5), and paragraph (d)(7)(iii) introductory text.

■ 2. In paragraph (d)(7)(iii), *Examples 1* through *9* are designated as paragraphs (d)(7)(iii)(A) through (I), respectively.

■ 3. In newly designated paragraph (d)(7)(iii)(A), removing ''*decision,*'' and ''§ 20.2053–3(c) or § 20.2053–3(d)(3)'' adding ''*decision.*'' and ''§ 20.2053–3(c) or (d)(3)'' in their places, respectively.

■ 4. In newly designated paragraphs (d)(7)(iii)(B) and (C), removing ''*payment,*'', ''*Example 1*'', and ''§ 20.2053–3(c) or § 20.2053–3(d)(3)'' and adding ''*payment.*'', ''paragraph (d)(7)(iii)(A) of this section (*Example 1*)'', and ''§ 20.2053–3(c) or (d)(3)'' in their places, respectively.

■ 5. In newly designated paragraph (d)(7)(iii)(D), removing ''*defendants,*'', ''*Example 1*'', and ''§ 20.2053–3(c) or § 20.2053–3(d)(3)'' and adding ''*defendants.*'', ''paragraph (d)(7)(iii)(A) of this section (*Example 1*)'', and ''§ 20.2053–3(c) or (d)(3)'' in their places, respectively.

■ 6. In newly designated paragraph (d)(7)(iii)(E), removing ''*payment,*'', ''*Example 1*'', and ''§ 20.2053–3(c) or § 20.2053–3(d)(3)'' and adding ''*payment.*'', ''paragraph (d)(7)(iii)(A) of this section (*Example 1*)'', and ''§ 20.2053–3(c) or (d)(3)'' in their places, respectively.

■ 7. In newly designated paragraph (d)(7)(iii)(F), removing ''*claims,*'' and ''§ 20.2053–3(c) or § 20.2053–3(d)(3)'' and adding ''*claims.*'' and ''§ 20.2053–3(c) or (d)(3)'' in their places, respectively.

■ 8. In newly designated paragraph (d)(7)(iii)(G), removing ''*enforceability,*'' and adding ''*enforceability.*'' in its place.
■ 9. In newly designated paragraph (d)(7)(iii)(H), removing ''*estate,*'' and adding ''*estate.*'' in its place.
■ 10. In newly designated paragraph (d)(7)(iii)(I), removing ''*satisfaction,*'' and adding ''*satisfaction.*'' in its place.
■ 11. Adding paragraph (d)(7)(iii)(J).
■ 12. Revising paragraph (f).

The revisions and addition read as follows:

§ 20.2053–4 Deduction for claims against the estate.

* * * * *

(b) * * *

(1) * * *

(iv) The value of each such claim against the estate is supported by a written appraisal document to be filed with the Form 706, *United States Estate (and Generation-Skipping Transfer) Tax Return,* or successor form, and the written appraisal document—

(A) Adequately reflects post-death events that have occurred prior to the date on which a deduction is claimed on an estate's Form 706;

(B) Reports, considers, and appropriately weighs all relevant facts and elements of value as are known or are reasonably determinable at the time of the appraisal, including the underlying facts of the claim against the estate, potential litigating risks, and the current status of the claim and procedural history;

(C) Takes into account post-death events reasonably anticipated to occur;

(D) Identifies an expected date or dates of payment (for purposes of determining the applicability of the present value limitation in § 20.2053–1(d)(6));

(E) Explains in detail the methods and analysis that support the appraisal's conclusions;

(F) Is prepared, signed under penalties of perjury, and dated by a person who is qualified by knowledge and experience to appraise the claim being valued and is not a family member of the decedent, a related entity, or a beneficiary of the decedent's estate or revocable trust (as those terms are defined in § 20.2053–1(b)(2)(iii)), a family member of a beneficiary or a related entity as to a beneficiary (as those terms would be defined in § 20.2053–1(b)(2)(iii) if references therein to the decedent were replaced with a reference to such beneficiary, and without regard to the limitations in § 20.2053–1(b)(2)(iii) based on the decedent's date of death), or an employee or other owner of any of them; and

(G) Includes a statement providing the basis for the person's qualifications to appraise the claim being valued;

* * * * *

(2) *Limitation on deduction.* The deduction under this paragraph (b) is limited to the value of the related claims or particular assets included in decedent's gross estate. *See* § 20.2053–1(d)(6)(v) for the impact of the present value limitation.

* * * * *

(c) * * *

(1) * * *

(iv) The value of each such claim against the estate is supported by a written appraisal document to be filed with the Form 706, *United States Estate (and Generation-Skipping Transfer) Tax Return,* or successor form, and the written appraisal document—

(A) Adequately reflects post-death events that have occurred prior to the date on which a deduction is claimed on an estate's Form 706;

(B) Reports, considers and appropriately weighs all relevant facts and elements of value as are known or reasonably determinable at the time of the appraisal, including the underlying facts of the claim against the estate, potential litigating risks, and the current status of the claim and procedural history;

(C) Takes into account post-death events reasonably anticipated to occur;

(D) Identifies an expected date or dates of payment (for purposes of determining the applicability of the present value limitation in § 20.2053–1(d)(6));

(E) Explains in detail the methods and analysis that support the appraisal's conclusions;

(F) Is prepared, signed under penalties of perjury, and dated by a person who is qualified by knowledge and experience to appraise the claim being valued, and is not a family member of the decedent, a related entity, or a beneficiary of the decedent's estate or revocable trust (as those terms are defined in § 20.2053–1(b)(2)(iii)), a family member of a beneficiary or a related entity as to a beneficiary (as those terms would be defined in § 20.2053–1(b)(2)(iii) if references therein to the decedent were replaced with a reference to such beneficiary, and without regard to the limitations in § 20.2053–1(b)(2)(iii) based on the decedent's date of death), or an employee or other owner of any of them; and

(G) Includes a statement providing the basis for the person's qualifications to appraise the claim being valued;

(v) The total amount deducted by the estate under paragraph (c) of this section does not exceed $500,000 (*see* § 20.2053–1(d)(6)(v) for the impact of the present value limitation);

* * * * *

(3) * * * Assume that each claim is paid within three years after the decedent's death, and that the value of each claim is determined from a written appraisal document that meets the requirements of paragraph (c)(1)(iv) of this section. * * *

(d) * * *

(5) *Claims founded upon a promise*—(i) *In general.* To be deductible, a claim founded on a promise must represent a personal obligation of the decedent existing at the time of the decedent's death, and the claim must be enforceable against the decedent's estate. In addition, except with regard to pledges or subscriptions (*see* § 20.2053–5), the deduction for a claim founded upon a promise or agreement is limited to the extent that the promise or agreement was bona fide and in exchange for adequate and full consideration in money or money's worth; that is, the promise or agreement must have been bargained for at arm's length and the price must have been an adequate and full equivalent reducible to money value.

(ii) *Decedent's promise to guarantee a debt.* A deduction for a claim founded upon a decedent's agreement to guarantee a debt of another is a claim founded on a promise and is subject to the limitation in paragraph (d)(5)(i) of this section. For purposes of section 2053, a decedent's agreement to guarantee a debt of an entity in which the decedent had an interest at the time the guarantee was given satisfies the requirement that the agreement be in exchange for adequate and full consideration in money or money's worth if, at the time the guarantee was given, the decedent had control (within the meaning of section 2701(b)(2)) of the entity. Alternatively, this requirement is satisfied to the extent the maximum liability of the decedent under the guarantee did not exceed, at the time the guarantee was given, the fair market value of the decedent's interest in the entity. The bona fide nature of the decedent's agreement to guarantee a debt of a family member, a related entity, or a beneficiary (as defined in § 20.2053–1(b)(2)(iii)) is determined in accordance with § 20.2053–1(b)(2)(ii). For a claim otherwise deductible under this paragraph (d)(5)(ii), the estate's right of contribution or reimbursement will reduce the amount deductible in accordance with § 20.2053–1(d)(3). Payments made pursuant to the decedent's guarantee of a debt are

deductible only to the extent that the debt for which the guarantee is given has not been taken into account in computing the value of the gross estate under § 20.2053–7 or otherwise.

* * * * *

(7) * * *

(iii) The claimant (C) is not a family member, related entity, or beneficiary of the estate of decedent (D), unless otherwise provided, and is not the executor (E).

* * * * *

(J) *Example 10: Guarantee.* On Date 1, D entered into a guarantee agreement with Bank (C) to secure financing for a closely-held business (LLC) in which D had a controlling interest. LLC was solvent at the time LLC executed a promissory note in the amount of $100x in favor of C. Prior to D's death, LLC became insolvent and stopped making payments on the note. After D's death, C filed a claim against D's estate for payment of the remaining balance due under the note and E paid the full amount due. Although E had a right of contribution against LLC for primary payment of the indebtedness, LLC was insolvent and no part of the debt was collectible at the time E deducted the payment. D's estate may deduct the amount paid to C in satisfaction of D's liability under the guarantee agreement. The guarantee agreement is considered to have been contracted for an adequate and full consideration in money or money's worth. The result would be the same if D did not have control of LLC as long as the fair market value of D's interest in the LLC on Date 1 was at least $100x.

* * * * *

(f) *Applicability date.* The rules of this section apply to the estates of decedents dying on or after [date of publication of the final rule in the **Federal Register**].

Paul J. Mamo,

Acting Deputy Commissioner for Services and Enforcement.

[FR Doc. 2022–13706 Filed 6–24–22; 4:15 pm]

BILLING CODE 4830–01–P

DEPARTMENT OF LABOR

29 CFR Parts 1910 and 1926

[Docket No. OSHA–2018–0004]

RIN 1218–AD10

Advance Notice of Proposed Rule Making (ANPRM)—Blood Lead Level for Medical Removal

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Advance Notice of Proposed Rulemaking (ANPRM).

SUMMARY: OSHA is considering rulemaking to revise its standards for occupational exposure to lead based on medical findings since the issuance of OSHA's lead standards that adverse health effects in adults can occur at Blood Lead Levels (BLLs) lower than the medical removal level (≥60 μg/dL in general industry, ≥50 μg/dL in construction) and lower than the level required under current standards for an employee to return to their former job status (<40 μg/dL).[1] The agency is seeking input on reducing the current BLL triggers in the medical surveillance and medical removal protection provisions of the general industry and construction standards for lead. The agency is also seeking input about how current ancillary provisions in the lead standards can be modified to reduce worker BLLs.

DATES: Submit comments on or before August 29, 2022.

ADDRESSES: You may submit comments and attachments, identified by Docket No. OSHA–2018–0004, electronically at *www.regulations.gov,* which is the Federal e-Rulemaking Portal. Follow the instructions online for making electronic submissions.

Instructions: All submissions must include the agency's name and the docket number for this ANPRM (Docket No. OSHA–2018–0004). When uploading multiple attachments into *Regulations.gov*, please number all of your attachments because *www.regulations.gov* will not automatically number the attachments. For example, Attachment 1—title of your document, Attachment 2—title of your document, Attachment 3—title of your document, etc. When submitting comments or recommendations on the issues that are raised in this ANPRM, commenters should explain their rationale and, if possible, provide data and information to support their comments or recommendations. Wherever possible, please indicate the title of the person providing the information and the type and number of employees at your worksite.

All comments, including any personal information you provide, will be placed in the public docket without change and will be publicly available online at *www.regulations.gov.* Therefore, OSHA cautions commenters about submitting information they do not want to be made available to the public or submitting materials that contain personal information (either about themselves or others) such as Social Security Numbers and birthdates.

Docket: To read or download comments or other material in the docket, go to Docket No. OSHA–2018–0004 at *www.regulations.gov.* All comments and submissions are listed in the *www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through that website. All submissions, including copyrighted material, are available for inspection at the OSHA Docket Office. Documents submitted to the docket by OSHA or stakeholders are assigned document identification numbers (Document ID) for easy identification and retrieval. The full Document ID is the docket number plus a unique four-digit code. OSHA is identifying supporting information in this ANPRM by author name and publication year, when appropriate. This information can be used to search for a supporting document in the docket at *https://www.regulations.gov.* Contact the OSHA Docket Office at 202–693–2350 (TTY number: 877–889–5627) for assistance in locating docket submissions.

FOR FURTHER INFORMATION CONTACT:

Press Inquiries: Contact Frank Meilinger, Director, Office of Communications, U.S. Department of Labor; telephone (202) 693–1999; email *meilinger.francis2@dol.gov.*

General and technical information: Contact Andrew Levinson, Acting Director, Directorate of Standards and Guidance, U.S. Department of Labor; telephone (202) 693–1950; email *Levinson.andrew@dol.gov.*

SUPPLEMENTARY INFORMATION: The Supplementary Information section follows this outline:

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[1] OSHA's standard for lead in general industry expresses blood lead in units of μg/100g of whole blood. The standard for lead in construction expresses blood lead in units of μg/dL, which the agency explained is essentially equivalent to μg/100g of whole blood (29 CFR 1926.62, Appendix A, II.B.3: *Health Protection Goals of the Standard).* For simplicity, this ANPRM expresses blood lead in units of μg/dL throughout.

I. Background

A. Events Leading to This Action

OSHA's lead standard for general industry (29 CFR 1910.1025), adopted in 1978, established a permissible exposure limit (PEL) airborne concentration of 50 μg/m^3 averaged over an 8-hour period and was based on consideration of health effects, feasibility issues, and the goal to keep BLLs below 40 μg/dL for the majority of workers occupationally exposed to lead (43 FR 54191). During approximately the same time-frame, the United States Congress enacted a law to provide Federal financial assistance to help cities and communities eliminate the causes of lead-based paint poisoning and detect and treat incidences of lead poisoning (Pub. L., 91–695; 42 U.S.C. Ch. 63). Additionally, the Consumer Products Safety Commission (CPSC) implemented regulations prohibiting lead from most consumer products and banned lead from residential paint (16 CFR 1303). The U.S. Environmental Protection Agency (EPA) and the U.S. Department of Housing and Urban Development (HUD) enacted rules to reduce human and environmental exposure to lead (24 CFR 35; 40 CFR 80; 40 CFR 745).

In 1992, OSHA promulgated an interim final rule for lead exposure in construction (29 CFR 1926.62) as required by Title X of the Housing and Community Development Act of 1992 (102 Pub. L. 550). This rule amended Subpart D of 29 CFR part 1926 by adding a new section, 1926.62, that lowered the existing lead PEL in construction to 50 μg/m^3 and included ancillary provisions similar to those in the general industry lead standard. OSHA's general industry and construction standards contain medical removal provisions for workers whose BLLs exceed a certain level: in general industry, when a periodic and a follow-up blood test result show BLL ≥60 μg/dL, or an average of the last three blood lead tests show BLL ≥50 μg/dL; and in construction, when a periodic and a follow-up blood test result show BLL ≥50 μg/dL. These workers must be temporarily removed to a job with exposures at or below the action level (58 FR 26590).

In 1992, the U.S. Congress passed the Workers' Family Protection Act (29 U.S.C. 671a). The Act required the National Institute for Occupational Safety and Health (NIOSH) to report on take-home contamination from workplace chemicals and substances, including lead.[2] NIOSH found take-home exposure to be a widespread problem (NIOSH, 1995). The report identified workplace measures that are effective in reducing take-home exposure such as changing clothes before going home and leaving soiled clothing at work for laundering, storing street clothes in areas separate from work clothes, showering before leaving work, and prohibiting removal of toxic substances or contaminated items from the workplace, in addition to citing the importance of primary prevention by limiting exposure in the workplace. NIOSH noted that preventing take-home exposure is critical because decontaminating homes and vehicles is not always effective.

In 1996, OSHA implemented a Special Emphasis Program (SEP) for lead in construction (CPL 2.105) in response to documented elevated BLLs in construction workers. The SEP established a mechanism for programmed health inspections of construction sites where lead may be present. In 2001, OSHA implemented a National Emphasis Program (NEP) for lead (CPL 2–0.130). The NEP was implemented to direct OSHA's field inspection efforts to reduce occupational exposures to lead. This ongoing NEP includes general industry, construction, longshoring, and marine terminals. OSHA updated its NEP for lead in 2008 and expanded its targeting in 2013 to include indoor and outdoor firing ranges and recycling industries (OSHA, 2008; OSHA, 2013). In 2007, OSHA completed a Regulatory Flexibility Act Section 610 review and Executive Order 12866 lookback review of 29 CFR 1926.62 Lead in Construction (OSHA, 2007). The agency found that for the hazards associated with lead in the construction industry, a mandatory standard remains necessary to adequately protect employees. The lookback study also concluded that the lead in construction standard has not had negative economic impacts on business, including small businesses, and therefore remains economically feasible.

Exposure to lead is associated with adverse health effects, including but not limited to effects on the reproductive, cardiovascular, neurological, respiratory, and immune systems. Since promulgation of OSHA's lead standards, extensive research has been published indicating adverse health effects in adults at lower levels than had been previously documented (see, *e.g.,* AOEC 2007; NTP 2012; ATSDR 2020; ACGIH 2013; EPA 2013). A variety of public health and government organizations have developed recommendations or revisions to standards to more stringently limit occupational exposures to lead and manage the effects of exposure in exposed workers. In 2007, the Association of Occupational and Environmental Clinics (AOEC) published guidelines for medical management of lead exposed adults (with special emphasis on those exposed to lead at work). The recommendations included: clinical assessment with detailed medical, occupational, and environmental history, physical exam, BLL determination, and other labs (CBC, BUN, Creatinine, Urine Analysis, EP); medical surveillance with follow-up BLL; and medical management with evaluation of exposures and risk factors, family and social context, and consideration for potential removal from exposure (AOEC, 2007). In 2016, the American College of Occupational and Environmental Medicine (ACOEM) released a Position Statement on Workplace Lead Exposure recommending revisions to OSHA's AL and PEL; workplace hygiene requirements; medical surveillance and medical removal protection provisions; and introduction of surface lead dust requirements (ACOEM 2016, p. e371). The Department of Defense (DOD) commissioned the National Research Council (NRC) to conduct a study to determine whether current OSHA exposure standards used on firing ranges are protective. The committee concluded that the current OSHA standard of a BLL of under 40 μg/dL is not sufficiently protective of personnel who have repeated lead exposures on firing ranges (NRC, 2013). DOD subsequently lowered the medical removal triggers for BLLs in military and civilian DOD personnel. DOD's medical removal is based on BLLs at or greater than 20 μg/dl, and employee return to work when BLL is at or below 15 μg/dL (DOD, 2018, p. 55; Table C4.T2, pp. 57–61). In 2018, NIOSH published a Request for Information (RFI) indicating NIOSH's intent to update its recommended exposure limit (REL) for inorganic lead and to develop updated recommendations for handling of inorganic lead and medical surveillance in the workplace (NIOSH 2018).

Several states have initiated updates to their occupational lead standards. In 2018 Michigan OSHA's State Plan

[2] Take-home lead contamination occurs when lead dust is transferred from the workplace on employees' skin, clothing, shoes, and other personal items to their vehicle and home. Take-home lead can be a chronic source of exposure for workers and exposures to household members (NIOSH 1995).

(MIOSHA) in the Michigan Department of Licensing & Regulatory Affairs revised its lead standards for general industry and construction. The revisions included changing the BLL at which an employee is required to be removed from lead exposure, previously 50 µg/dL, to 30 µg/dL for both standards. In addition, the BLL at which an employee may be returned to work involving lead exposure was changed from < 40 µg/dL to 15 µg/dL in both standards. MIOSHA also removed a previous requirement to analyze for the zinc protoporphyrin (ZPP) level. MIOSHA's revisions followed recommendations developed by a group of stakeholders over the course of meetings held in 2017 and 2018. The group's proposed revisions to the occupational standards were the subject of public hearings in August 2018 and became effective in December 2018 (MOEMA 2019, p. 8). Michigan's revisions did not alter the PEL for lead.

The California Department of Public Health (CDPH) Occupational Lead Poisoning Prevention Program made recommendations for revisions to the California OSHA (Cal/OSHA) lead standards for general industry in 2010 and construction in 2011, including recommendations to lower the BLLs for medical removal and return to former job status; require more frequent BLL testing; broaden the provision and notification processes for BLL testing for exposed workers; and lower the 8-hour time-weighted average (TWA) PEL (CDPH, 2010; CDPH, 2011). CDPH's recommendation for lowering the PEL was based on a report produced by the California Environmental Protection Agency (Cal/EPA, Office of Environmental Health Hazard Assessment (OEHHA)) that used an updated physiologically-based pharmacokinetic (PBPK) model to characterize the relationship between air lead levels and BLLs (OEHHA, 2014).

Cal/OSHA has held advisory meetings to discuss potential changes to its lead standards and has published a discussion draft of possible amendments to the existing regulations in general industry and construction operations. California's most recent discussion draft includes a medical removal level of 30 µg/dL for a single test result; or when the last two monthly blood lead tests are ≥ 20 µg/dL; or when the average of the results of all blood lead tests conducted in the last 6 months is at or above 20 µg/dL of whole blood. The discussion draft includes a return to former job status when two consecutive blood lead tests are ≤ 15 µg/dL. The discussion draft also includes a reduction in the PEL from 50 µg/m^3 to 10 µg/m^3 and the AL from 30 µg/m^3 to 2 µg/m^3, among other changes. The discussion draft and related documents are available at *https://www.dir.ca.gov/dosh/DoshReg/5198Meetings.htm.*

Washington State Department of Labor & Industries, Division of Occupational Safety and Health (Washington DOSH), is also developing a variety of updates to Washington State's occupational lead standards. In 2012, Public Health—Seattle and King County (PHSKC) petitioned the Washington State Department of Labor & Industries to update the occupational lead standards, including the BLLs for medical removal and return to former job status; the AL and PEL; and provisions for protective clothing, hygiene, medical surveillance, training, and education. Washington DOSH has proposed lowering its medical removal BLL to ≥ 30 µg/dL for a single test result, ≥ 20 µg/dL for multi-test results, and a return to former work status BLL of < 15 µg/dL. Washington DOSH has also proposed a reduction in the PEL from 50 µg/m^3 to 20 µg/m^3, among other changes to the lead standard. Washington DOSH's stakeholder review draft (2019) and other information related to its stakeholder meetings on the lead rule revision process are available at *https://lni.wa.gov/safety-health/safety-rules/rulemaking-stakeholder-information/sh-rules-stakeholder-lead.*

OSHA is also considering revisions to its lead standards. Through this ANPRM, OSHA seeks input on the BLL triggers used for medical removal and return to work status. The agency also requests information on other potential changes to the current standards to reduce the risk of adverse health effects from occupational lead exposure.

B. Industry Profile Information

In accordance with OSHA's intent to assess the potential impacts of revising blood lead triggers for medical removal protection, the agency made preliminary estimates of the annual number of firms, by industry, expected to have workers with elevated BLLs. For these estimates, OSHA used the reporting levels in CDC's Adult Blood Lead Epidemiology and Surveillance (ABLES) dataset of 5 µg/dL, 10 µg/dL, and 25 µg/dL, and OSHA's lead standards' medical removal levels (50 µg/dL for construction and 60 µg/dL for general industry).

OSHA identified the industry sectors associated with lead exposure as those found in the ABLES dataset. This dataset shows that the national prevalence rate of BLLs ≥10 µg/dL for adults declined from 26.6 adults per 100,000 employed in 2010 (among 37 reporting states) to 15.8 in 2016 (among 26 reporting states). For context, the geometric mean BLL for all adults in the US (including workers) was 0.855 µg/dL in 2018 (HHS, 2022). Historically, in the U.S., most lead exposures among adults have been occupational. Among the 11,695 adults with known lead exposures at BLL of ≥10 µg/dL in 2016, 90.3% had occupational exposures. The majority of these adults were employed in four main industry sectors: manufacturing, construction, services, and mining (NIOSH, 2016).

To help inform the rulemaking process, OSHA contracted with Abt Associates to generate preliminary estimates of the number of establishments and cases across all states at the ABLES reporting levels of 5 µg/dL, 10 µg/dL, 25 µg/dL, and the lead standards' medical removal levels (50 µg/dL for construction and 60 µg/dL for general industry). The first step was to identify industry sectors associated with lead exposure by 4-digit NAICS that were identified in a 2017 CDPH report (Payne, 2017), industries identified by OSHA in the personal sampling data reported by the OSHA Information System (OIS) (OSHA, 2020a), and industries with violations of lead exposure medical surveillance requirements in the last 10 years of OSHA inspections and violations (OSHA, 2020b; OSHA, 2020c). To estimate the number of workers with BLLs at or above each ABLES reporting level and the OSHA standards' medical removal levels by NAICS, BLL data from the ABLES program and the CDPH Occupational Blood Lead Registry for the years 2012–2014 and 2015–2018 (Payne, 2017; CDPH, 2020a; CDPH, 2020b) were pooled. Because ABLES data are limited to those states that report testing results to ABLES, the next step was to use U.S. Census data to extrapolate a preliminary estimate of the national number of cases from the ABLES state data. The method and results are described in full in the memorandum entitled *Estimated Number of Work-Related BLL Cases and Firms* (Abt Associates, 2021). This memorandum includes a table that provides the number of firms with preliminary BLL estimates at or above the relevant levels (the ABLES reporting levels and the OSHA standards' medical removal levels) and a table that provides the number of workers with preliminary BLL estimates at or above the relevant levels; the preliminary BLL estimates are presented by industry. In Appendix A at the end of this ANPRM, Table 1 ''Summary of Annual Number of Firms

with BLL Tests and Cases'' presents the estimated number of firms where employees received test results that were at or above each ABLES reporting level and the OSHA standards' medical removal levels.

Of 44,144 firms where employee BLLs are tested, 8,611 firms were estimated to have recorded BLLs equal to or above 5 µg/dL, while 2,087, were estimated to have recorded BLLs at or above 25 µg/dL; only 137 firms were estimated to have baseline BLL cases annually resulting in medical removal protection under OSHA's existing requirements (BLLs greater than or equal to 50 and 60 µg/dL for construction and general industry, respectively).

This preliminary analysis shows that, among all affected employers, approximately 44 percent of firms where employee BLL is tested are in five industry groups: NAICS 7139: Other Amusement and Recreation Industries (6,656 firms); NAICS 3272: Glass and Glass Product Manufacturing (5,156 firms); NAICS 8111: Automotive Repair and Maintenance (3,333 firms); NAICS 2383: Building Finishing Contractors (2,746 firms); and NAICS 5629: Remediation and Other Waste Management Services (1,663 firms). OSHA requests public input on the agency's preliminary profile of affected industries, in particular the list of affected NAICS industries and the estimated number of firms that have workers with BLLs at or above the selected thresholds.

C. Health Effects of Lead Exposure

Exposure to lead is associated with adverse health effects, including but not limited to effects on the reproductive, cardiovascular, neurological, respiratory, and immune systems. As highlighted by a National Research Council report (NRC, 2013), lead has been shown to have both acute and chronic toxic effects, affecting virtually every organ and system in the body (ATSDR, 2020). Since OSHA's lead standard for general industry was promulgated, BLLs in the general adult population have declined from an overall mean blood-lead level of 15.8 µg/dL (1976–1980) to 0.855 µg/dL in 2018, primarily reflecting the decrease in lead used in gasoline production, as well as the removal of lead from consumer paint (CDC, 1982; HHS, 2022, p. 212; ATSDR, 2020, p. 2). However, extensive research has emerged indicating that adverse health effects can occur in adults with lower BLLs than was previously recognized (ATSDR, 2020; ACGIH, 2013; CDPH, 2009 and 2013; EPA, 2013; NTP, 2012). For example, BLLs as low as 5 µg/dL have been associated with impaired kidney and reproductive function, high blood pressure, and cognitive effects attributed to prenatal exposure. Poorer performance on neurocognitive and neuropsychologic assessments were observed in adults with BLLs as low as 5–19 µg/dL compared with adults with BLLs below 5 µg/dL (Kosnett, 2007, pp. 464, 466; EPA, 2013, pp. 4–311—4–313, 2013; NTP, 2012, pp. 19–42). While there is also evidence of adverse health effects in adults with BLLs below 5 µg/dL, those are not discussed in OSHA's literature review (please see ATSDR, 2020). Table 1 provides an overview of the adverse health effects associated with adult lead exposure, including the effects of exposure on pregnant workers and their developing fetuses, and longer-term effects on children/adolescents exposed in utero to lead.

TABLE 1—OVERVIEW OF ADVERSE HEALTH EFFECTS ASSOCIATED WITH EXPOSURE TO LEAD IN ADULTS

Health Effect	Descriptive Detail of Health Effect	
Reproductive and Developmental [3]	Reduced fertility, low sperm mobility, increased risk of miscarriage. Effects on developing fetus due to lead exposure in utero—decreased birth size, adverse effects on developing brain, kidney, nervous system, cognitive and learning disabilities, decreased child growth, delayed onset puberty.	
Vascular/Cardiovascular	Hypertension	Increased systolic and/or diastolic pressure, stroke, heart disease.
	Cerebrovascular	Stroke.
	Cardiac/cardiovascular	Heart disease, atherosclerosis, altered cardiac conduction.
Hematological	Heme synthesis (interference with iron uptake), anemia, altered levels of plasma erythropoietin.	
Neurological	Reduced performance on neurocognitive and neuropsychological tests, peripheral neuropathy, psychiatric symptoms (depression, panic disorders, anxiety, hostility, anger, schizophrenia) cognitive decrements, lead intoxication, dementia, hearing loss.	
Renal	Nephrotoxicity (proximal tubular nephropathy, glomerular sclerosis, interstitial fibrosis, tubular necrosis).	
Respiratory	Decreased lung function, increased bronchial hyperreactivity, increased risk of asthma and obstructive lung disease.	
Endocrine (excluding reproductive)	Alteration of serum thyroid levels (T3, T4, TSH), decreased levels of serum vitamin D.	
Hepatic	Liver enlargement, increased gall bladder wall thickness, increased total cholesterol.	
Musculoskeletal	Bone loss, increased bone metabolism/turnover, adverse periodontal and dental effects.	
Gastrointestinal	Constipation, colic, abdominal cramps.	
Body weight	Decreased body mass index (BMI) in adolescents and adults.	
Immunological	Decreased complement, changes in indicators of inflammation (monocytes, macrophages, neutrophils) and cell-mediated immunity (T cells, natural killer cells).	
Cancer	Lung, stomach, kidney, and brain cancer.	

Based on information contained in ATSDR, 2020.

1. Routes and Kinetics of Lead Exposure

Lead exposures in adults above background or baseline levels are typically associated with occupational exposures. Background or baseline levels occur from incidental exposures through ambient air, foods, drinking water, soil, and dust and result in an average BLL for adults of 0.855 µg/dL (geometric average) (ATSDR, 2020; HHS, 2022). Occupational exposure to lead can occur through inhalation, oral, and/or dermal routes (EPA, 2013, pp. 7–18; NAS, 2013, pp. 9, 15–17, 47). The Agency for Toxic Substances and Disease Registry (ATSDR) has stated that all the health effects discussed here can result from all three of these routes of exposure (ATSDR, 2020).

Lead accumulates in the body with continued or chronic exposure (ATSDR, 2020; AOEC, 2007; EPA, 2013; NTP, 2012; Shih, 2007). In adults, 90 percent of lead is stored in bone, with only 1 percent in blood (EPA, 2013, pp. 4–324—4–326). Lead can be released from bone to blood and other soft tissues over time. In particular, lead can be mobilized from bone even after removal from occupational exposure; after use of chelation therapy to reduce BLLs; during age-related bone loss, especially menopause and osteoporosis; and during pregnancy and lactation (EPA, 2013; NTP, 2012). Because lead is retained in the bones and can be released into the bloodstream over time, it is difficult to predict individuals' BLLs from their recent external exposures (NAS, 2013; ATSDR, 2020).

Multiple factors can influence the toxico- and pharmacokinetics of lead in the body, including genetic polymorphisms, nutrition and diet, smoking, gender, and age (NAS, 2013). California OEHHA developed a pharmacokinetic model which indicated that when BLLs during the working lifetime (characterized in the model as 40 hours per week over a 40-year working life) are maintained below 20 µg/dL, medical removal is expected to result in a fairly rapid decline to a BLL of 15 µg/dL, which was selected as an acceptable BLL for the purposes of the model (OEHHA, 2014, pp. 3–4). For example, the 95th percentile worker [4] removed after forty years of exposure with a BLL of 20 µg/dL would be expected to decline to 15 µg/dL within ten weeks. If BLLs are allowed to reach the 50 µg/dL currently allowed under OSHA standards, the California OEHHA model estimates that medical removal periods greater than 18 months would be generally necessary to reduce BLLs to 15 µg/dL, even among workers with only one year of occupational exposure (OEHHA, 2014, pp. 3–4).

Table 2 highlights some of the adverse health effects associated with various BLLs. While these findings are based on clinical assessments from comprehensive reviews, they do not necessarily represent strict threshold values as certain health endpoints may manifest at lower or higher levels in some individuals or groups.

TABLE 2—OVERVIEW OF HEALTH EFFECTS ASSOCIATED WITH ELEVATED BLL IN ADULTS

BLL (µg/dL)	Health effects
5–10	Acute decrease in renal function.
	Elevated blood pressure.
	Altered heme synthesis.
	Impaired neurocognitive and neuropsychological assessment.
	Developmental effects (*e.g.,* decreased cognitive and reduced birthweights)—fetuses exposed to lead in utero through pregnant worker lead exposure.
10–20	Spontaneous abortion (miscarriage).
	Hypertension.
	Decreased renal function.
	Decreased platelet count.
	Decreased blood hemoglobin.
20–40	Headache.
	Fatigue.
	Anemia.
	Sleep disturbance.
	Anorexia.
	Bowel changes.
	Arthralgia.
	Myalgia.
	Decreased libido.
	Personality changes
40–60	Sperm effects (decreased number and function).
	Subclinical peripheral neuropathy.
	Altered red blood cell function.
	Renal damage.
	Cognitive dysfunction.
60–80	Hemolytic anemia.
	Renal failure.
	Stroke.
Above 80	Central Nervous System (CNS) effects.
	Nephropathy.
	Gout.
	Hearing loss.
	Encephalopathy.

Adapted from AOEC, 2007. For additional resources please also see: *NTP Monograph on Health Effects of Low-Level Lead,* available at *https://ntp.niehs.nih.gov/ntp/ohat/lead/final/monographhealtheffectslowlevellead_newissn_508.pdf.*

[3] For more information on pregnancy and lead exposure please see *https://www.cdc.gov/nceh/lead/publications/leadandpregnancy2010.pdf.*

[4] The phrase '95th percentile worker' in this context means that ninety five percent of the workers removed from lead exposure after a 40-year work life of lead exposure resulting in a BLL of 20 µg/dL would be expected to take 10 weeks for their BLLs to decline 5 µg/dL to 15 µg/dL.

2. Medical Surveillance and Management for Elevated Blood Lead

A comprehensive medical surveillance program can be an invaluable tool in assessing the healthfulness of a workplace. Medical surveillance incorporates a systematic assessment of employees' health through medical monitoring and management practices (NIOSH, 2018). OSHA included a medical surveillance provision in the 1978 lead standard in part to mitigate some of the most detrimental effects of lead exposure to workers. However, since OSHA promulgated the standard, much more has become known regarding acute and chronic exposures (especially at low levels) and susceptible populations.

Measurement and Management of Blood Lead Levels (BLLs)

OSHA, as well as a number of agencies and public health groups state that the BLL is the best method available to monitor lead exposure (1910.1025, Appendix C; ACOEM 2016, p. e372; AOEC 2007, p. 4; CDPH 2009, p. 4; CSTE 2015, p. 2). OSHA and others have noted that BLL is generally a good indicator of current or recent external lead exposure; however, it is not necessarily correlated with total body burden of lead or cumulative exposure (29 CFR 1910.1025, Appendix C; AOEC 2016, pp. 4–7; CDPH 2009, p. 4; NAS 2013, pp. 48–56). This is because, over time, a high percentage of lead is deposited in bone, and after exposure ends, mobilization from bone occurs very slowly. As a result, a high BLL may represent a high recent exposure without an excess of total body burden, and a low BLL does not necessarily mean that total body burden is low (29 CFR 1910.1025). For long-term, long-latency, or cumulative exposures, lead body burden is generally considered the most adequate method (NAS 2013, p. 64). Lead body burden can be measured using x-ray fluorescence techniques but such methods are currently not widely or readily available (ACOEM 2016, p. e372; CSTE 2015, p. 2).

Medical management guidelines for adult lead exposure were developed by a national expert panel coordinated by the Association of Occupational and Environmental Clinics (AOEC 2007, pp. 5–9, 13), in collaboration with the ABLES program. The authors recommend that maintaining BLLs below 20 µg/dL over a twenty-year period, or under 10 µg/dL over a forty-year period, would be sufficient to prevent chronic effects associated with adult lead exposure. They further recommend maintaining BLLs below 20 µg/dL in order to prevent recognized acute health effects (Schwartz and Hu, 2007). ACOEM states that the most compelling evidence for adverse health effects occurs at moderate levels of blood lead ranging from 10 to 20 µg/dL (ACOEM 2016, p. 1). In the context of general population screening, the CDC recommends adult BLLs (persons ≥16 years of age) from a venous blood specimen of ≥5 µg/dL be considered for case classification for the purposes of medical surveillance (CDC 2016, p. 260); ABLES uses 5 µg/dL to indicate an elevated BLL for surveillance purposes (ABLES, 2021). NIOSH additionally provides a reference guide to BLL regulations and recommendations (ABLES, 2021).

The following sections outline the current medical management and monitoring practices required under OSHA's lead standards, in order to contextualize OSHA's later questions regarding possible changes to these requirements in Section II, Request for Input.

Methods for Monitoring Blood Lead Levels in OSHA's Standards

OSHA's lead standards do not specify a particular method for analyzing BLL but require that the method of sampling and analysis used is accurate to plus or minus 15 percent or 6 µg/100 ml, whichever is greater (to a 95 percent confidence level). The general industry standard once required the analysis to be conducted by a laboratory licensed by the CDC or which has received a satisfactory grade in blood lead proficiency testing from the CDC within the previous 12 months (per 29 CFR 1910.1025(j)(2)(iii)), but now allows testing to be conducted in a CLIA compliant laboratory (OSHA, 2018).[5] The construction standard requires the analysis to be conducted by a laboratory approved by OSHA (29 CFR 1926.62(j)(2)(iii)). The medical surveillance guidelines in Appendix C of OSHA's lead standards indicate that any method that meets the accuracy specified by the standards can be used to analyze the blood sample.

[5] In a memorandum to OSHA Regional Administrators, the agency specified that in lieu of approval by OSHA or CDC, the agency will accept the use of a blood lead analysis laboratory that has been approved under the U.S. Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services (CMS), blood lead laboratory monitoring system pursuant to the Clinical Laboratory Improvement Amendments (CLIA) regulations, 42 CFR part 493 (OSHA 2018).

OSHA's Requirements for Blood Lead and Zinc Protoporphyrin Testing, Worker Notification of Blood Lead Levels, Medical Removal, and Return to Work

The medical surveillance and medical removal protection provisions in OSHA's lead standards contain BLL triggers for medical removal, return to work status, and employee notification of blood test results. The general industry standard requires employers to institute a medical surveillance program for all employees who are or may be exposed at or above the action level of 30 µg/m^3 for more than 30 days per year (29 CFR 1910.1025(j)). Employers must make biological monitoring in the form of blood lead testing and ZPP levels available to these employees in accordance with the following schedule provided in 29 CFR 1910.1025(j)(2)(i):

- At least every six months to each employee covered under paragraph (j)(1)(i) of the standard;
- At least every two months for each employee whose last blood lead test indicated a BLL at or above 40 µg/dL. This frequency shall continue until two consecutive blood lead tests indicate a BLL below 40 µg/dL; and
- At least monthly during the removal period of each employee removed from exposure to lead due to an elevated BLL.

OSHA's lead standard for construction requires the employer to make blood sampling and analysis for lead and ZPP levels available to employees occupationally exposed on any day to lead at or above the action level (29 CFR 1926.62 (j)(1)(i)). It further requires the employer to institute a medical surveillance program for all employees who are or may be exposed by the employer at or above the action level for more than 30 days in any consecutive 12 months (29 CFR 1926.62 (j)(1)(ii)) and requires employers to provide blood lead testing to employees in the medical surveillance program at least every two months for the first six months, and every six months thereafter (29 CFR (1926.62 (j)(2)(i)(A)). Furthermore, the employer is required to provide blood lead testing at least every two months for employees covered under (j)(1)(i) or (ii) whose last test indicated a BLL at or above 40 µg/dL, until two consecutive tests show the BLL has declined below 40 µg/dL. And, the standard requires the employer to provide blood lead testing at least monthly during the removal period of each employee removed from exposure to lead due to an elevated BLL (29 CFR 1926.62(j)(2)(i)(C)).

OSHA's general industry standard requires the employer to notify each employee whose BLL is at or above 40 µg/dL within five working days after the receipt of biological monitoring results. OSHA's construction standard requires the employer to notify each employee in writing of their BLL within five working days after the receipt of biological monitoring results, regardless of the BLL detected.

The general industry standard requires an employer to remove an employee from work involving exposure to lead at or above the action level when two consecutive blood lead tests are at or above 60 µg/dL; or when the average of the last three tests (or the average of all tests conducted over the previous six months, whichever period is longer) is at or above 50 µg/dL, with the exception that medical removal is not required if the last test indicates a BLL below 40 µg/dL. It also requires medical removal when a final medical determination concludes that an employee has a medical condition that places the employee at increased risk of material impairment to health from exposure to lead (29 CFR 1910.1025(k)). The construction standard requires an employer to remove an employee from work involving exposure to lead at or above the action level when the employee's BLL is at or above 50 µg/dL for two consecutive tests or a final medical determination concludes that the employee has a medical condition that places the employee at increased risk of material impairment to health from exposure to lead (29 CFR 1926.62(k)). Both standards specify that the employer shall return an employee to the employee's former job status when two consecutive blood sampling tests indicate that the BLL is below 40 µg/dL (29 CFR 1910.1025(k)(1)(iii)(A)(1); 29 CFR 1926.62(k)(1)(iii)(A)(1)).

Zinc Protoporphyrin (ZPP) Testing

Along with BLLs, ZPP testing is required by OSHA's lead standards as part of its medical surveillance and management plan (29 CFR 1910.1025(j)(2); 29 CFR 1926.62(j)(2)). ZPP is a metabolite found in erythrocytes during hemoglobin synthesis. The zinc in ZPP replaces iron in hemoglobin synthesis during times of iron deficiency. Elevated lead levels in the blood interfere with iron ion transfer, creating a condition similar to iron deficiency, thus elevating zinc in the production of hemoglobin and ZPP.

The clinical utility of ZPP testing to identify elevated BLL is now understood to be limited by several factors:

- *Low sensitivity:* ZPP is generally not elevated until BLLs exceed 25 µg/dL (Kosnett et al 2007, p. 468). Thus, workers may reach harmful BLLs well before the ZPP level registers as abnormal.
- *Low specificity:* ZPP is not specific to lead. In other words, elevated levels of ZPP can be caused by conditions other than blood lead, such as iron deficiency anemia, jaundice, and sickle cell anemia (ATSDR 2020, p. 336). Thus, an elevated ZPP does not always mean that a worker has an elevated BLL.
- *Lag time:* ZPP levels generally lag behind BLLs by two to six weeks (CDPH 2009, p. 4). Thus, a worker may have an elevated BLL while the ZPP level is still within normal range. The reverse is also true; a worker's BLL may begin to decline, while the lagging ZPP level remains elevated (Martin 2004, pp. 589–590). This delay limits the utility of ZPP as a screening or biomonitoring tool.
- *High individual variability:* Individuals with the same BLL can have widely differing ZPP levels (Martin 2004, pp. 588–590). This may be due to differences in individual susceptibility to lead (Grandjean 1991, pp. 111–112) or other factors. However, such variations can complicate interpretation of test results.

Both AOEC and CDPH recommend against routine clinical use of ZPP—unless legally required—for monitoring lead-exposed patients (AOEC, 2007; CDPH 2009, p. 4). Similarly, ATSDR notes that ''ZPP is not sufficiently sensitive at lower BLLs and therefore is not as useful a screening test for lead exposure as previously thought'' (ATSDR 2007, pp. 232–233). OSHA's enforcement policy currently allows employers to use methods other than the ZPP test for determining lead toxicity. See *www.osha.gov/laws-regs/standardinterpretations/1996–03–04–1.* Due to these issues, OSHA is requesting input on whether to eliminate the requirement for ZPP monitoring (see Section II, Request for Input).

II. Request for Input

This ANPRM seeks input on the following areas: OSHA's triggers for medical removal of workers with elevated BLLs and their return to lead-exposed work; OSHA's requirements for medical surveillance and management of lead-exposed employees; several additional provisions and compliance protocols that are undergoing public review in State Plans' ongoing work to update their occupational lead standards; and the costs and effectiveness of lead exposure identification and control strategies. This Request for Input section includes a series of questions on the OSHA standards' requirements and possible revisions to them, followed by a series of questions on employers' requirements, which may in some cases be more protective than OSHA standards. While the questions pertaining to current requirements are primarily addressed to employers, OSHA will review and consider all information submitted in response to these questions.

This section includes questions about several provisions of OSHA's lead standards that are addressed in recent or proposed changes to State Plan lead standards in Michigan, Washington State, and California. As previously discussed, in January 2019 MIOSHA revised its lead standards for general industry and construction, changing the BLL at which an employee is required to be removed from lead exposure and the BLL at which an employee may be returned to lead exposure. Cal/OSHA has held advisory meetings to discuss a variety of potential changes to its lead standards and has published a draft of possible amendments to the existing regulations in general industry and construction operations. [6] [7] Washington DOSH is also developing a variety of updates to DOSH's occupational lead standards.[8] For several lead standard provisions that State Plans have made or proposed changes to, this section describes the changes in the relevant State Plan(s) and requests input on whether similar revisions to federal lead standards should be considered. The State Plan changes and proposals include revisions to state blood lead triggers for medical removal protection and return to work; permissible exposure limits; and several ''safe harbor'' protocols that employers in certain industries, or who meet specified requirements, may opt to use as alternatives to complying with the main rule.

Several questions in this section also relate to recommendations made by the

[6] California's most recent discussion draft and other materials related to the advisory meetings are available at *https://www.dir.ca.gov/dosh/DoshReg/5198Meetings.htm.*

[7] The California Department of Public Health (CDPH) Occupational Lead Poisoning Prevention Program (OLPPP) made recommendations to Cal/OSHA for revising its General Industry Lead Standard and Construction Industry lead standards for the protection of workers who are exposed to lead on the job, available at *https://www.cdph.ca.gov/Programs/CCDPHP/DEODC/OHB/OLPPP/Pages/LeadStdRecs.aspx.*

[8] Washington DOSH's stakeholder review draft (2019) and other information related to its stakeholder meetings on the lead rule revision process are available at *https://lni.wa.gov/safety-health/safety-rules/rulemaking-stakeholder-information/sh-rules-stakeholder-lead.*

Association of Occupational and Environmental Clinics (AOEC, 2007) and ACOEM (2016, pp. e371-e372) for updates to OSHA's Lead standards. ACOEM's recommendations refer to ''significant lead exposure'', defined as an airborne or surface lead content known or reasonably anticipated to cause elevated BLL (ACOEM 2016, p. e372, Table 1); and refer to a ''lead-exposed worker'', defined as ''any worker who is handling or disturbing materials with a significant lead content in a manner that could reasonably be expected to cause potentially harmful exposure through lead dust inhalation or ingestion, regardless of airborne lead concentrations or surface contamination levels'' (ACOEM 2016, p. e372).

OSHA notes that this ANPRM focuses primarily on medical surveillance/medical removal protection and on state-based innovations. Therefore, it does not request input on every provision OSHA might seek to modernize or otherwise revise in its lead standards through a Notice of Proposed Rulemaking (NPRM) in the future.

When answering the numbered questions below, please label your responses with the number of the question, explain the reasons supporting your views, and identify and provide relevant information on which you rely, including, but not limited to, data, studies, and articles.

A. Blood Lead Triggers for Medical Removal Protection

1. Requirements for Medical Removal

OSHA's general industry standard for lead requires an employer to remove an employee from work involving exposure to lead at or above the action level (30 μg/m^3) when two consecutive blood lead tests are at or above 60 μg/dL or when the average of the last three tests is at or above 50 μg/dL. OSHA's construction standard requires an employer to remove an employee from work involving exposure to lead at or above the AL when the employee's BLL is at or above 50 μg/dL for two consecutive tests. (See Section I.C, Health Effects of Lead Exposure, for a full description of OSHA's blood lead requirements for Medical Removal Protection (MRP)).

ACOEM has recommended medical removal of workers who have repeat BLLs over 20 μg/dL (measured in four weeks), or if any single BLL exceeds 30 μg/dL (ACOEM 2016, p. e372, Table 1). MIOSHA's 2019 update to Michigan's occupational lead standard changed the BLL at which an employee in general industry or construction is to be removed from lead exposure, previously 50 μg/dL, to 30 μg/dL for both standards. Cal/OSHA's discussion draft includes a medical removal BLL of ≥ 30 μg/dL; when the last two monthly blood lead tests are ≥ 20 μg/dL; or when the average of the results of all blood lead tests conducted in the last six months is at or above 20 μg/dL of whole blood. Washington DOSH's stakeholder review draft would lower its medical removal BLL to ≥ 30 μg/dL for a single test result and ≥ 20 μg/dL for multi-test results for both general industry and construction lead standards. After commissioning the National Research Council (NRC) to conduct a study to determine whether current OSHA exposure standards used on firing ranges are protective (NRC, 2013), DOD lowered the medical removal triggers for BLLs in military and civilian DOD personnel, which previously were aligned with OSHA's standards. DOD's medical removal is now based on BLLs at or greater than 20 μg/dL (DOD, 2018, p. 55; Table C4.T2, pp. 57–61)).

(1) Should OSHA consider changing the BLL at which an employee in general industry or construction is to be removed from lead exposure to match any of the approaches described above? Is there a different BLL trigger for removing a worker from lead-exposed work that you would suggest? Please explain your answer and provide supporting information or data, if available.

2. Requirements for Return to Lead-Exposed Work

OSHA's lead standards for general industry and construction both specify that the employer shall return an employee to their former job when two consecutive blood-sampling tests indicate that the BLL is below 40 μg/dL.

ACOEM has recommended that return to lead-exposed work should be considered after two BLLs are below 15 μg/dL (ACOEM 2016, p. e372, Table 1). MIOSHA changed the BLL at which an employee may return to lead exposure from below 40 μg/dL to below 15 μg/dL in both general industry and construction. Cal/OSHA's discussion draft would provide that a removed worker may return to former job status when two consecutive blood lead tests are below 15 μg/dL. Washington DOSH's stakeholder review draft similarly includes a return-to-work BLL of below 15 μg/dL for both general industry and construction lead standards. DOD's updated policy provides for employee return to work when BLL is at or below 15 μg/dL (DOD, 2018, p. 55; Table C4.T2, pp. 57–61)).

(2) Should OSHA consider changing the BLL below which an employee shall be returned to lead exposure to 15 μg/dL? Is there a different BLL trigger for returning a worker to lead-exposed work following medical removal that you would suggest? Please explain your answer and provide supporting information or data, if available.

B. Medical Surveillance Provisions

1. Medical Examination and Consultation Requirements

OSHA's lead standards require employers to make a full medical examination and consultation available to an employee: (1) before the first assignment to an area that has lead at or above the action level; (2) at least once a year for an employee who had a BLL of 40 μg/dL or over at any time during the preceding 12 months; and (3) as soon as possible on notification by an employee that they have developed signs or symptoms of lead intoxication, desire medical advice concerning the effects of lead (past or current) and the ability to procreate a healthy child, or who has difficulty in breathing during respirator fit test or use. In addition, an examination must be made available as medically appropriate for each employee either removed from exposure to lead due to a risk of sustaining material impairment to health, or whose lead exposure is otherwise limited based on a final medical determination.

For the purposes of the lead standard, a full medical examination includes: (1) a detailed work and medical history; (2) a thorough physical examination; (3) measurement of blood pressure; (4) analysis of BLL, hemoglobin and hematocrit, erythrocyte indexes, peripheral smear morphology, zinc protoporphyrin (ZPP), blood urea nitrogen and creatinine, and urinalysis with microscopic examination; and (5) any other tests that a physician thinks are appropriate, including a pregnancy test or laboratory evaluation of male fertility if requested by the employee.

(3) Are these still appropriate tests or should a full medical examination include any other tests? OSHA is also requesting comment on the appropriateness of including the ZPP given its limitations (see also Section #6, ''ZPP'', below).

2. Triggers for Routine Blood Lead Monitoring

OSHA's lead standards require the employer to institute a medical surveillance program, including blood lead testing prior to lead exposure and at regular intervals thereafter, for employees who are or may be exposed

to airborne lead at or above 30 μg/m³ for more than 30 days per year.

Airborne Lead Exposure Trigger for Blood Lead Monitoring

The Washington DOSH stakeholder review draft would require employers to provide ongoing blood lead monitoring for employees exposed to lead for more than 10 days per year, including any day with airborne exposure totaling 10 μg/m³ as an 8-hour TWA or greater or any day with a task lasting 30 minutes or more that involves exposure above 20 μg/m³. Cal/OSHA's discussion draft would require employers to institute a medical surveillance program, including blood lead testing, for employees who are or may be exposed at or above a revised action level of 2 μg/m³ for 10 or more days per year.

(4) Should OSHA consider expanding its criteria for blood lead monitoring to resemble the ongoing blood lead monitoring criteria that Washington DOSH and/or Cal/OSHA is considering? Are there different criteria you would suggest? Please explain your answers.

Additional Triggers

In OSHA's lead standards, worker eligibility for blood lead monitoring is based solely on airborne lead exposure criteria. In contrast, the Washington DOSH stakeholder review draft would require employers to provide ongoing blood lead monitoring for employees exposed at or above any action level for more than 10 days per year, including any day involving a combined total of at least one hour of: (1) activity disturbing or touching metals containing 20 percent or more lead (by weight); (2) activity disturbing non-metals containing 0.5 percent or more lead by weight; (3) creating aerosols or fumes from materials containing 0.1 percent or more lead by weight; or (4) work in areas with surfaces at a ''Surface Action Level'' of 1000 μg/dm² (equivalent to 9290 μg/ft²).[9]

Cal/OSHA's discussion draft includes a requirement that employers must institute a medical surveillance program, including blood lead testing, for employees who perform a ''trigger amount of lead work'', defined as altering or disturbing material that is known or reasonably anticipated to contain at least 0.5 percent lead by weight, or torch cutting any scrap metal, for a combined total of at least 8 hours during any 30-day period.

In addition, ACOEM has recommended that BLL be measured routinely for all lead workers, where a ''lead-exposed worker'' is defined as ''any worker who is handling or disturbing materials with a significant lead content in a manner that could reasonably be expected to cause potentially harmful exposure through lead dust inhalation or ingestion, regardless of airborne lead concentrations or surface contamination levels'' (ACOEM 2016, p. e372).

(5) Should OSHA consider adding criteria other than airborne lead exposure to its requirements for blood lead testing, such as contact with lead-contaminated surfaces, disturbance of lead-containing materials or direct contact with high-percentage lead materials? In particular, should OSHA consider adopting criteria based on contact with lead-contaminated surfaces, disturbance of lead-containing materials, or contact high lead-content metals, as Washington DOSH's stakeholder review draft and Cal/OSHA's discussion draft contemplate? Please explain your answer.

3. Frequency of Blood Lead Monitoring

OSHA's lead standard for general industry requires employers to provide blood lead testing to employees in the medical surveillance program at least every six months, with the following exceptions: (1) every two months if a previous BLL was at or above 40 μg/dL of whole blood, until two consecutive results are below 40 μg/dL and (2) at least monthly during the removal period of each employee removed from exposure to lead due to an elevated BLL.

For those employees who are in the medical surveillance program because they are or may be exposed to airborne lead at or above the action level (30 μg/m³) for more than 30 days in any consecutive 12 months, OSHA's lead standard for construction requires the employer to provide blood lead testing at least every two months for the first six months, and every six months thereafter. In addition, for employees who were exposed on *any* day to lead at or above the action level, and for employees who have been exposed to lead at or above the action level for more than 30 days in a 12 month period *and* whose last blood sample indicated a BLL at or above 40 ug/dL, the standard requires blood testing at least every two months until two consecutive results indicate a BLL below 40 μg/dL. The standard also requires the employer to provide blood lead testing at least monthly during the removal period of each employee removed from exposure to lead due to an elevated BLL. (See Section I.C, Health Effects of Lead Exposure, for a full description of OSHA's blood lead requirements for MRP).

ACOEM has recommended that lead workers' BLLs be measured every two months for the first six months of placement, or upon change to tasks resulting in higher exposure, and that BLLs should be measured every six months thereafter (ACOEM 2016, p. e372, Table 1). In addition, ACOEM has recommended BLL measurement every two months for workers with results between 10 and 19 μg/dL and monthly measurement for workers with results of at least 20 μg/dL.[10]

The Washington DOSH stakeholder review draft and Cal/OSHA's discussion draft would require that blood lead testing be made available every two months for a worker's first six months of testing, and every six months after that. In addition, testing would be made available at least every two months if a worker's BLL is greater than 10 μg/dL.

The Washington DOSH stakeholder review draft would require testing to be offered monthly if an employee has been medically removed, until two consecutive tests show the worker's BLL has decreased to below the proposed return-to-work level.[11] Cal/OSHA's discussion draft stipulates testing at least monthly for each employee whose last BLL was at or above 20 μg/dL of whole blood, and during the removal period of each employee removed from exposure to lead due to an elevated BLL.

(6) Should OSHA consider revising the required frequency and the BLLs related to the schedule of blood lead testing? Would requirements similar to those included in Washington DOSH and Cal/OSHA's drafts be appropriate? If not, what would be an appropriate frequency for blood lead testing? Please explain your answer.

4. Analytical Methods for BLL Testing

As discussed previously in Section I.C.2, *Medical Surveillance and Management for Elevated Blood Lead,* OSHA standards do not specify a

[9] See *Surface Sampling and Material Content Requirements* below for percentage and contamination specifications. The Washington DOSH Stakeholder Review Draft states that ''work is timed from beginning the contact or disturbance activity to the time when the worker accesses washing facilities where personal protective equipment can be doffed properly and the worker can thoroughly wash off lead contamination.''

[10] ACOEM's recommendations refer to ''significant lead exposure'', defined as an airborne or surface lead content known or reasonably anticipated to cause elevated BLL (ACOEM 2016, p. e372, Table 1); and refer to a ''lead-exposed worker'', defined as ''any worker who is handling or disturbing materials with a significant lead content in a manner that could reasonably be expected to cause potentially harmful exposure through lead dust inhalation or ingestion, regardless of airborne lead concentrations or surface contamination levels'' (ACOEM 2016, p. e372).

[11] The proposed return-to-work level is 15 μg/dL in Washington and 10 μg/dL in California.

particular method for analyzing BLL but require that the method of sampling and analysis used is accurate to plus or minus 15 percent or 6 µg/100 ml, whichever is greater (to a 95 percent confidence level). In a memorandum to OSHA Regional Administrators, the agency specified that in lieu of approval by OSHA or CDC, the agency will accept the use of a blood lead analysis laboratory that has been approved under the U.S. Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services (CMS), blood lead laboratory monitoring system pursuant to the Clinical Laboratory Improvement Amendments (CLIA) regulations, 42 CFR part 493 (OSHA 2018). All blood lead analysis performed in a CLIA-compliant lab must meet the Proficiency Testing requirement of ±4 µg/dL or 10%, whichever is greater.

(7) Should OSHA consider revising its standard to require the use of a blood lead analysis laboratory that has been approved under the CMS blood lead laboratory monitoring system pursuant to the CLIA regulations, consistent with OSHA's 2018 memorandum? Please explain your answer.

(8) Are there methods other than collecting a venous sample that would meet the accuracy requirements of the lead standard? Please describe the advantages and limitations of such methods.

(9) Are portable direct reading instruments for measuring BLL available that meet the accuracy requirements of the OSHA lead standards and would be considered equivalent to an analysis conducted by a laboratory approved by OSHA or CDC?

(10) Do you use or have knowledge of other measures of lead in the body? Please describe and explain whether and how they could be used effectively for medical monitoring of workers exposed to lead and the relative costs of those measures (*i.e.,* cost-effectiveness).

5. Employee Notification of BLL Results

OSHA's general industry standard requires the employer to notify each employee whose BLL is at or above 40 µg/dL within five working days after the receipt of biological monitoring results. OSHA's construction standard requires the employer to notify each employee in writing of their BLL within five working days after the receipt of biological monitoring results, regardless of the BLL detected.

The Washington DOSH stakeholder review draft and Cal/OSHA's discussion draft include a requirement that employers must make sure workers receive all blood testing results, regardless of level, within five days of receiving them from the medical providers.

(11) Should OSHA revise its general industry standard to require employers to notify all employees who receive blood lead testing of their results, similar to the requirements of its construction standard and requirements under consideration by Washington DOSH and Cal/OSHA? If not, what criteria should be used to determine which employees should be notified of their results? Please explain your answer.

6. ZPP

ACOEM's Position Statement (2016) advised OSHA that ZPP testing is insufficiently sensitive as a measure of lead exposure when BLLs are below 25 mg/dL and is no longer needed since BLL testing is superior and readily available (ACOEM 2016, p. e372). In January 2019, MIOSHA removed a previous requirement to analyze for the zinc protoporphyrin level. Washington DOSH's stakeholder review draft and Cal/OSHA's discussion draft also would eliminate ZPP testing requirements.

(12) Should OSHA remove the requirement for ZPP testing currently included in its lead standards? Please explain your recommendation to continue or discontinue ZPP testing as part of medical surveillance for lead-exposed workers.

7. Provisions for Worker Privacy

Under the medical surveillance provisions of OSHA's lead standards, employers are provided with the results of an individual employee's BLL measurements, in addition to the physician's opinion as to whether the employee has any detected medical condition that would place the employee at increased risk from lead exposure; recommended special protective measures or lead exposure limitations; and any recommended limitation upon the employee's use of respirators. Physicians are prohibited from revealing to the employer any findings, including laboratory results, or diagnoses *unrelated* to an employee's occupational exposure to lead.

More recent OSHA standards include measures to enhance employee privacy and encourage employees to participate in medical surveillance by minimizing fears about retaliation or discrimination based on medical findings. In OSHA's beryllium standard, for example, the information provided to the employer may not contain the results of medical exams performed. The physician may, if authorized by the employee in writing, inform the employer of any recommendations for limitations on exposure to beryllium and for further testing at another facility and/or continued medical surveillance.

(13) Should OSHA update the lead standards' employee privacy protections, including restriction of employer access to an individual employee's BLL measurements? Please explain your recommendation.

C. Permissible Exposure Limit (PEL)

For workers exposed to lead above the PEL of 50 µg/m^3 for more than 30 days per year, OSHA's general industry lead standard requires employers to implement engineering and work practice controls (including administrative controls) to maintain exposures at or below the PEL. For workers exposed to lead above the PEL for 30 days or less per year, the standard requires employers to implement engineering controls to reduce exposures to lead to 200 µg/m^3 and then allows the use of any combination of controls (engineering, work practice, respiratory controls) to maintain exposures at or below 50 µg/m^3.

California and Washington State's drafts include revisions to their permissible exposure limits. Cal/OSHA's discussion draft includes a reduction in the PEL from 50 µg/m^3 to 10 µg/m^3 and the action level from 30 µg/m^3 to 2 µg/m^3.[12] The Washington DOSH stakeholder review draft includes a reduction in the PEL from 50 µg/m^3 to 20 µg/m^3.

(14) Should OSHA consider reducing its PEL of 50 µg/m^3 for occupational lead exposure or its action level of 30 µg/m^3? At what level do you believe the PEL should be set to reduce the harmful effects of lead exposure in exposed workers? Do you think this level would be technologically and economically feasible for affected industries (see OSH Act Sec. 6(b)(5), 29 U.S.C. 655(b)(5))? Please explain your answer and, if available, provide data pertinent to the benefits, feasibility, and expected increase in costs of revising the federal PEL or action level for airborne lead. (Please note that OSHA requests detailed information on costs of already-existing requirements and voluntary

[12] CDPH contracted with Cal/EPA to evaluate the relationship between occupational airborne lead exposure and BLLs. Using health-based biokinetic modeling, Cal/EPA found that workplace air lead levels should be limited to an 8-hour time-weighted average (TWA) of 2.1 µg/m^3 in order to prevent BLLs exceeding 10 µg/dL in at least 95% of workers with regular and long-term exposure. See CDPH 2013 for further details. CDPH's PEL recommendation can be viewed at: *https://www.cdph.ca.gov/Programs/CCDPHP/DEODC/OHB/OLPPP/CDPH%20Document%20Library/LeadStdPELRec.pdf.*

practices in a series of provision-specific questions in Section H, Questions for Employers on Current Practices).

(15) Cal/OSHA's discussion draft includes a Separate Engineering Control Airborne Limit (SECAL) for selected processes in lead acid battery manufacturing.[13] Should OSHA consider implementing a SECAL for occupational lead exposure for specific processes if industry-wide compliance with a proposed revision to the PEL is demonstrably infeasible for specific processes?

(16) Should OSHA consider removing the provision of OSHA's general industry lead standard that allows employers to use respiratory protection to comply with the PEL for workers exposed to lead above the PEL for 30 days or less per year? Please explain your answer and, if applicable, your recommendation on how employers should be required to limit exposures of workers exposed above the PEL for 30 days or less per year.

D. Personal Protective Equipment (PPE), Hygiene, and Training

(17) The Washington DOSH stakeholder review draft would require employers to provide and ensure the use of impermeable PPE when employees are working with lead compounds that may be absorbed through the skin for any work covered by the scope of the rule. Should OSHA consider a similar requirement for its lead standards? Please explain your answer and any evidence available on the feasibility and cost of this requirement if adopted by OSHA.

(18) The Washington DOSH stakeholder review draft would require employers to prohibit workers covered by the scope of the rule from cleaning or laundering protective clothing or equipment at home. Should OSHA consider a similar requirement for its lead standards? Please explain your answer and any evidence available on the feasibility and cost of this requirement if adopted by OSHA.

(19) The Washington DOSH stakeholder review draft includes requirements that employees be provided with hygiene facilities and PPE when any of the following criteria are met:

1. Employees work in areas with surfaces at a ''Surface Action Level'' of 1000 μg/dm^2 (equivalent to 9290 μg/ft^2); [14]

2. Employees disturb or touch metals with a ''Metals Action Level'' of 20 percent or more lead content by weight;

3. Employees disturb any materials with a ''Non-metal Action Level'' of 0.5 percent or more lead content by weight (5000 ppm); or

4. Employees welding, burning, or grinding, or otherwise creating aerosols or fumes from materials with a ''Burning/Grinding/Blasting Action Level'' of 0.1 percent or more lead content by weight (1000 ppm).

Material content criteria (items #2 through 4) are applied during any activity that could release lead or lead compounds from the material in a form that could be inhaled, ingested, or absorbed through the skin. The metals action level (item #2) also applies when workers directly contact the metal with skin, personal protective equipment, or clothing.

Should OSHA add hygiene and PPE provisions similar to any or all of those described above, which are being considered for adoption by Washington DOSH? Please explain your answer and, if available, provide information on the feasibility and cost of these requirements if adopted by OSHA.

(20) Are there issues or concerns related to surface contamination or material content criteria for hygiene and PPE requirements that OSHA should consider?

OSHA's lead standards require employers to provide PPE in a clean and dry condition daily to employees whose exposure levels (without regard to respirator use) are over 200 μg/m^3 of lead as an 8-hour TWA, and weekly for other lead-exposed employees. Cal/OSHA's discussion draft would require the employer to provide PPE in a clean and dry condition daily to employees whose exposure levels (without regard to respirator use) exceed 30 μg/m^3 of lead as an 8-hour TWA. It would maintain the requirement to provide required PPE at least weekly for all other lead workers exposed above the proposed PEL (10 μg/m^3). Washington DOSH's stakeholder review draft would require the employer to replace or launder PPE at least daily for employees whose exposure levels exceed 50 μg/m^3 of lead as an 8-hour TWA. In addition, it would require the employer to repair, replace, or launder protective clothing at least weekly, and when visibly contaminated or damaged, for employees whose exposure levels exceed 20 μg/m^3 of lead as an 8-hour TWA.

(21) Should OSHA consider revising the requirements for employers to provide clean or new PPE to workers? Please provide specific recommendations for frequency and exposure triggers, and please explain your answers.

(22) Washington DOSH's stakeholder review draft would require that the training provided to all lead-exposed workers include information on special precautions for pregnant workers. Should OSHA consider including a similar requirement to include material on precautions for pregnant workers in the training provisions of its lead standards?

E. Safe Harbor Compliance Protocols

The Washington DOSH stakeholder review draft includes several safe harbor protocols which provide employers alternative methods of compliance, including some provisions that would relax requirements for exposure monitoring and for use of engineering and work practice controls to meet the proposed PEL. Employers following a safe harbor compliance protocol completely would be considered in compliance with the lead rule for tasks covered and would not be cited for departing from the main body of requirements of the lead rule for those tasks. However, if an employer does not follow the provided safe harbor protocol properly, the criteria and requirements of the main body of the Washington DOSH rule would be used to assess compliance. The Washington DOSH stakeholder review draft includes protocols that could potentially be used by an employer in any industry, including the *Well Managed Blood Lead Levels Safe Harbor Protocol* and the *Clean Areas Safe Harbor Protocol* described below, as well as industry- or task-specific protocols, including the *Safe Harbor Protocol for Handling Lead-Containing Articles in Retail Settings,* the *Safe Harbor Protocol for Office and Residential Settings,* and the *Safe Harbor Protocol for Incidental Lead Paint in Construction/Renovation, Repair, and Painting (RRP) Work* described below.

1. Well Managed Blood Lead Levels Safe Harbor Protocol

The Washington DOSH stakeholder review draft describes a protocol that

[13] Specifically, the Cal/OSHA Discussion Draft's SECAL for oxide production, paste mixing, grid pasting and parting, and battery assembly would require employers to comply with a 50 μg/m^3 exposure limit at the effective date, then with a limit of 40 μg/m^3 at five years from the effective date. The Cal/OSHA Discussion Draft SECAL for grid production and small parts casting, and plate formation would require employers to comply with an exposure limit of 50 μg/m^3 at the effective date, then with a limit of 30 μg/m^3 at five years from the effective date.

[14] The Washington DOSH stakeholder review draft defines surface contamination as ''free lead in dust or residues on a surface that can be transferred to other surfaces on contact'' and specifies that single sample testing is sufficient for determining whether surfaces are contaminated.

provides an employer greater flexibility than would otherwise be required for implementing PPE, work practices, and other lead exposure controls, where the employer demonstrates that their program effectively controls employee BLLs. The compliance protocol would provide a safe harbor for employers who voluntarily submit worksite blood lead records demonstrating that employee BLLs are effectively managed. To demonstrate effective control of employee BLLs, the employer would be required to conduct blood lead testing for all workers at the facility with known or potential exposure to lead; provide ongoing documentation of effective blood level management to Washington DOSH; and, upon request, communicate with Washington DOSH if questions or concerns arise from review of the documentation provided. Employers following this protocol would not be subject to scheduled inspections for lead related issues, and the requirements associated with a new PEL of 20 µg/m^3 (8-hour TWA) would not be enforced where airborne exposures are below the proposed Secondary Permissible Exposure Limit (SPEL) of 50 µg/m^3 (8-hour TWA).[15]

In the Washington DOSH stakeholder review draft, effective management of BLLs is indicated by: blood lead testing for all workers at the facility with exposure to lead covered by the rule, including baseline tests for all exposed workers, annual tests for all exposed or potentially exposed workers, and more frequent tests for all workers meeting the requirements for periodic testing in the Washington DOSH lead rule; and a record of well managed BLLs, meaning that: (1) the average BLLs for workers exposed above 20 µg/m^3 is below 10 µg/dL and the BLLs for each worker in the group is kept below 20 µg/dL; and (2) BLLs for the group of all other workers (those exposed below 20 µg/m^3) are kept below 10 µg/dL.[16]

To qualify for this safe harbor, the employer would be required to submit documentation annually for each establishment for which the safe harbor will be claimed.[17] The required documentation includes the employer's lead control programs for the establishment; the employer's assessments of lead exposures for the establishment; names of all workers onsite during the previous two years (including workers of other employers); for each worker, whether they are known to have had exposures at any action level, at the PEL or at the SPEL; the record of all blood lead testing for the establishment for the past two years (or new testing only when resubmitting annually); and a report detailing actions taken in response to increased lead exposure or elevated blood BLLs found during the previous year.

(23) Should OSHA consider a safe harbor protocol approach similar to the *Well Managed Blood Lead Levels* protocol described above, which is being considered for adoption in Washington State? What aspects of the protocol would be beneficial? Are there issues, concerns, or different approaches to a ''safe harbor'' based on well-managed BLLs that OSHA should consider?

2. Clean Areas Safe Harbor Protocol

The Washington DOSH stakeholder review draft describes a protocol that would relieve employers from implementing the requirements of the lead rule for workers in clean areas who do not have lead-related tasks. The clean areas protocol described by Washington DOSH could be used to designate parts of a facility, such as offices or work areas where lead-containing materials are not present, as clean so that workers in those areas are not covered by the lead rule. The protocol could also be used for facilities where lead is present in building materials, such as lead based paint, but is normally undisturbed by activities of the employer. Where a clean area is designated within a work establishment, workers and other individuals are not required to use protective equipment, work practices, or controls to prevent lead exposure and will not necessarily be trained about lead hazards.

The Washington DOSH stakeholder review draft sets out criteria for establishing clean areas, wherein all worker-accessible surfaces must be shown using ongoing surface sampling for free lead. Lead coatings and lead-containing materials may be present where lead is well contained and not released to surface sampling. When sampling indicates that lead is being brought into the clean area or released from damaged materials in the area, non-lead workers must be kept from the vicinity until the hazard is abated and sampling in the area of the release indicates the area is clean.

The following criteria would be used to determine if routine cleaning is sufficient to maintain surface lead on all worker accessible surfaces below 4.3 µg/dm^2 (equivalent to 40 µg/ft^2). Single sample testing, conducted as specified in Washington DOSH's stakeholder review draft, may be used to identify clean areas. If initial sampling indicates that lead on worker accessible surfaces is below 4.3 µg/dm^2, the area represented by such sampling is considered ''clean'' and the employer would not be required to implement requirements of the lead rule (outside of this protocol) therein.[18] When there is activity that could reintroduce lead into the area, repeat sampling would be required every two years.

In an area where initial sampling indicates the presence of surface lead on worker accessible surfaces at or above 4.3 µg/dm^2, Washington DOSH's proposed protocol would provide for representative four-sample testing to demonstrate that ongoing cleaning is sufficient to maintain minimal lead levels.

(24) Should OSHA consider a safe harbor protocol approach similar to the *Clean Areas* protocol described above, which is being considered for adoption in Washington State? What aspects of the protocol would be beneficial? Are there issues, concerns, or different approaches to a ''safe harbor'' based on identification of clean areas using surface sampling that OSHA should consider?

3. Safe Harbor Protocol for Handling Lead-Containing Articles in Retail Settings

The Washington DOSH stakeholder review draft describes a protocol that

[15] Under this protocol, the following medical surveillance provisions would apply: workers with BLLs found above 20 µg/dL would be tested monthly until their BLL is below 15 µg/dL for two monthly tests; workers would be eligible for the medical removal requirements included in the rule; and workers with a BLL greater than 10 µg/dL for more than 4 months must have their case reviewed by a physician.

[16] Under the Washington DOSH stakeholder review draft, infrequent elevated BLLs above 20 µg/dL would not disqualify an employer when: (1) the elevated BLL is documented as a baseline level prior to work with the company at this facility or any other facility operated by the employer, or (2) the employer documents the exposure incident responsible for the elevated BLL and takes corrective action to effectively prevent further exposures.

[17] Under the Washington DOSH stakeholder review draft, documentation would be submitted annually to maintain coverage by the safe harbor, using forms and formats supplied by the DOSH. The employer would need to be responsive to questions from the department regarding the submitted documentation and must allow for onsite auditing of the submission by DOSH. If DOSH reviews the documentation and does not agree that it shows that the establishment qualifies for this safe harbor, the department would notify the employer in writing, including a description of how the documentation fails to qualify. If information in the submission appears to constitute a violation of a Washington Industrial Safety and Health Act (WISHA) rule, the employer would be informed and asked to provide proof of abatement for serious violations.

[18] Note: Washington DOSH's stakeholder review draft contemplates that maintenance and housekeeping staff working in a clean area may be doing work covered by the lead rule.

could be applied to workers handling lead-containing products for sale in retail settings where it is expected that lead will be generally well controlled. The Retail Settings protocol would not cover areas of a retail facility used for maintenance or repair work that may disturb lead-containing materials, and would not cover retail gun shops co-located with gun ranges. For areas of a retail establishment where lead products are not sold, retail employers could selectively apply the Clean Areas compliance protocol described above. Under the Retail Settings protocol, retail employers could assume that workers are covered by the Basic Rules set out in the DOSH stakeholder review draft, which include requirements for cleaning practices, hygiene, PPE, and provisions for hazard communication and training. Exposure assessments would not be required for workers who only handle lead-containing materials in retail activities including receiving, stocking, sales, and housekeeping in the retail activity areas. In addition, retail workers would not be covered under the Action Rules (which include ongoing exposure monitoring and blood lead testing) or the PEL and SPEL Rules (which include requirements covering routine control of airborne lead exposure and respirator use, as well as heightened requirements in the provisions for cleaning, hygiene, PPE, hazard communication and training, exposure monitoring and medical surveillance).

The Washington DOSH stakeholder review draft sets out several conditions that must be met by the employer to implement the Retail Settings Protocol, such as requiring that lead-containing materials be kept segregated from other materials in the establishment and inspected when received in the establishment for damage to packaging or the product that could release lead; that any manufacturing, repair, assembly, or maintenance work involving lead-containing products that generates lead aerosols or dust must be performed in a separate area of the establishment away from the retail space and must follow protocols to prevent lead contamination of the retail space; and that the employer must implement specific housekeeping practices (*e.g.,* prohibition of dry sweeping, use of wet wiping/mopping and/or HEPA filtered vacuums) around lead-containing products or areas where these products are stored.

(25) Should OSHA consider a safe harbor protocol approach similar to the Retail Settings Protocol described above, which is being considered for adoption in Washington? What aspects of the Protocol would be beneficial? Are there issues, concerns, or different approaches to a ''safe harbor'' for retail settings that OSHA should consider?

4. Safe Harbor Protocol for Office and Residential Settings

The Washington DOSH stakeholder review draft describes a protocol for employees working within a facility that has lead-based paint or paint with lead pigments doing work that does not disturb painted surfaces. This protocol would, for example, allow the employer to assume that workers in office and residential settings are not covered by the lead rule unless doing maintenance, remodeling, or repair work. Under this protocol, workers occupying a facility for office work are not covered by the rule, except when there is an incident causing a significant release and exposure to lead; and except for workers doing housekeeping work, who would be covered under the Basic Rules requirements for cleaning practices, hygiene, PPE, and provisions for hazard communication and training.

To implement this protocol, employers and building owners may assume that paint contains lead or conduct screening tests to determine lead content. For this protocol, it is expected that there may be minor releases due to normal wear and tear and light repair work in the facility. The building owner or employer would be required to make written documentation of the lead assessment available in the facility for occupants, housekeeping workers, and maintenance workers. Maintenance or housekeeping staff would be required to make at least quarterly visual inspections of the facility for damage to lead paint surfaces in occupied areas. Whenever damage is discovered, by inspection, occupant report, or other observations, the building owner or employer would be required to assess the damage and ensure any repair and clean-up is done in a timely manner using methods that limit the spread of lead-containing materials (*e.g.,* wet wiping, use of HEPA filtered vacuums).

(26) Should OSHA consider a safe harbor protocol approach similar to the Office and Residential Settings protocol described above, which is being considered for adoption in Washington? What aspects of the protocol would be beneficial? Are there issues, concerns, or different approaches to a ''safe harbor'' that OSHA should consider for work in office and residential settings that does not involve maintenance, remodeling, or repair work?

5. Safe Harbor Protocol for Incidental Lead Paint in Construction/Renovation, Repair, and Painting (RRP) Work

The Washington DOSH stakeholder review draft describes a protocol for use by contractors and maintenance operations handling lead-containing paint. This protocol would apply to employers conducting incidental lead paint work covered by the EPA renovation, repair and painting work rules, or doing similar work. It is not intended for lead abatement work as defined by the U.S. Department of Commerce and EPA, which would be expected to involve greater levels of exposure than is contemplated by this protocol.

This protocol assumes that: (1) work will be done with hand tools or power tools with HEPA filtered dust collection systems; (2) the work occurs in residential or similar construction where the primary lead-containing material is finish paint on wood or wallboard substrates, rather than structural steel; (3) contractors conducting this work are in compliance with the Department of Commerce and EPA programs and have certification from them when required; and (4) training required for environmental certification will be supplemented with additional information on Washington DOSH rules, including for personal protective equipment, respiratory protection, hygiene practices, and work practices.

This protocol would require workers disturbing painted surfaces to wear half-face respirators with P100 filters or more protective respirators and would allow for workers to request Powered Air Purifying Respirators (PAPRs) with HEPA cartridges. The employer must implement a respiratory protection program (including identification of a respirator program administrator; identification of the respirator models and configuration the employer will require for each task performed; and the process for medical clearance and fit testing of workers) and must provide personal protective equipment including either safety glasses/goggles or full face respirators; disposable overalls or overalls that are laundered per Washington DOSH rule requirements; work boots; disposable shoe covers or dedicated work boots that are not worn off the worksite for workers scraping or sanding paint; gloves or a glove combination sufficient to prevent lead accumulation on the hands and provide necessary protection from cuts or other hand hazards; and other personal protective equipment

necessary based on other hazards at the worksite.

Employers using this protocol would provide workers with workplace-specific training (see DOSH Stakeholder Review Draft—Action Rules). Work covered under the EPA/Department of Commerce rules must be conducted by workers meeting the minimum training and certification standards of that program, with additional training on worker safety issues including health effects of lead, respiratory protection, PPE, work practices specific to the worksite, and limits of work practices. An on-site competent person must be able to recognize lead-related hazards and have authority to take action to correct lead issues at the worksite.

Under this protocol, direct monitoring of employee exposure would not be required. The employer could presume that employee exposure to airborne lead is no greater than 10 times the proposed PEL of 20 μg/m^3 as an eight-hour TWA.[19] While this presumption is used, the employer must meet all requirements of the rule consistent with this level of exposure, including: baseline blood lead testing for all workers contacting lead-containing coatings[20] or in the vicinity of any work disturbing these materials, follow-up blood lead testing every two months for the first six months and every six months thereafter, and blood lead testing at the conclusion of work; lead control areas around any work disturbing lead-containing coatings; respirator use for all workers disturbing lead-containing coatings; and provision of appropriate PPE, a clean change area, and hygiene facilities including dedicated handwashing, boot cleaning, and showers as necessary.

(27) Should OSHA adopt a safe harbor protocol approach similar to the protocol described above for incidental lead paint in RRP work that is being considered for adoption in Washington? What aspects of the protocol would be beneficial? Are there issues, concerns, or different approaches to a protocol for RRP work that OSHA should consider?

F. Environmental Effects

The National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321, *et seq.*), the Council on Environmental Quality (CEQ) regulations (40 CFR part 1500), and the Department of Labor (DOL) NEPA Compliance Procedures (29 CFR part 11) require that OSHA give appropriate consideration to environmental issues and the impacts of proposed actions significantly affecting the quality of the human environment. OSHA intends to collect written information and data on possible environmental impacts that could occur outside of the workplace (*e.g.,* exposure to the community through contaminated air/water, contaminated waste sites, etc.) if the agency were to revise the existing standard for occupational exposure to lead. Such information should include both negative and positive environmental effects that could be expected to result from guidance or a revised standard. Specifically, OSHA requests comments and information on the following:

(28) What is the potential direct or indirect environmental impact (for example, the effect on air and water quality, energy usage, solid waste disposal, and land use) from a reduction in BLL triggers or other changes to the OSHA lead standards?

(29) Are there any situations in which reducing lead exposures to employees would be inconsistent with meeting environmental regulations?

G. Duplicative, Overlapping, or Conflicting Rules

This section examines whether there are any duplicative, overlapping, or conflicting regulations concerning lead that OSHA should be aware of. In your explanation, please explain in detail if there are any such concerns of which the agency should be aware.

(30) Are there any federal regulations that might duplicate, overlap, or conflict with modifications to the current lead standards? If yes, please identify and explain how they would duplicate, overlap, or conflict.

(31) Are there any federal programs in areas such as defense or energy that might be impacted by modifications to the current lead standards? If yes, please identify and explain how they would be impacted.

H. Questions for Employers on Current Practices

OSHA requests that commenters, when answering questions regarding economic impact, be as specific as possible. For example, if an employer is using a modified medical surveillance program, then helpful information would include the following: the medical testing necessary; the exposure status or types of employees who would receive medical testing; the frequency of the testing; and the medical surveillance costs. The agency invites comment on the labor time and level of labor expertise required to implement proposed methods, even if dollar-cost estimates are not available. For discussion of equipment-related costs, OSHA requests that commenters estimate relevant factors such as purchase price, cost of installation, cost of equipment maintenance, cost of training, and expected life of the equipment. Also, please discuss the quantitative benefits (*e.g.,* reductions in BLLs) and the associated costs (*e.g.,* cost of an exposure control method). Because there are some differences between OSHA's lead standards for general industry and construction, please specify which standard is applicable to your work.

(32) If you use criteria more stringent than OSHA's requirements for conducting blood lead testing on your employees, how do your criteria differ from OSHA's requirements?

(33) If you use criteria more stringent than OSHA's requirements for notifying employees of their BLL and ZPP results, how do your criteria differ from OSHA's requirements?

(34) If you use criteria more stringent than OSHA's requirements for medical removal protection in your work environment or industry, how do your criteria differ from OSHA's requirements? Please include the criteria, such as the BLL, for both medical removal and return to work status.

(35) What are your current costs of medical removal per employee (where possible, please monetize in terms of dollars per time unit (*e.g.,* per month, per year))? Would your company be able to reassign the medically removed worker to a job at least at the clerical level that the employee would find acceptable? Please include specific examples of hourly wages (per job category) for the employee's regular occupation and the hourly wages for the medically assigned clerical job, if available.

(36) How many of your employees, over the past 10 years, have been removed from lead-exposed work due to elevated BLLs? If possible, please submit anonymized examples of employees who were brought into the medical removal program, their BLL level at the time of removal, and the

[19] Employers could choose to conduct exposure assessments to determine actual lead exposure levels and tailor their program under this protocol as indicated by those results. However, direct monitoring of exposure would not be required when not feasible in the timeframe of the project. Employers would assume paint in structures built before 1978 contains lead in quantities that will require controls and PPE as specified in this protocol. Paint could be tested by collecting samples for laboratory analysis, use of X-ray fluorescence, or following EPA/Department of Commerce rules for colorimetric testing kits. The protocol would require any paint found to potentially contain 5000 ppm lead or more than 1 mg/cm^2 of lead on the surface to be treated as a lead-containing material.

[20] ''Lead-containing coatings'' refers to coatings that are known or presumed to contain lead.

time required to bring the BLL level below 40 μg/dL (or an alternative specified level).

(37) Over the past ten years, how many, or what percentage, of your employees were removed from lead-exposed work due to elevated BLLs exceeding the maximum 18-month time period and were unable to return to work?

(38) OSHA's lead standards set a BLL of below 40 μg/dL (two consecutive tests) for return to lead-exposed work for medically removed workers. As discussed earlier in this ANPRM, in Section I.A. Background; Events Leading to this Action, OSHA is considering lowering the BLL for medical removal. If possible, please submit estimated increases in the number of affected employees and in costs if the BLL for allowing return to work were reduced to a level lower than OSHA's current BLL of 40 μg/dL. Please specify the BLL for return to work you assume in your estimation.

(39) How many and what percentage of your employees are currently in your medical surveillance program? How many of these employees receive BLL testing? How many receive ZPP monitoring?

(40) What are your current costs of medical surveillance per employee? Please include specific examples of resource requirements in terms of additional staffing or time commitments (per job category), costs for purchase of testing materials (dollar cost per unit), expected life of equipment, and costs for energy usage and any other additional expenses.

(41) The OSHA lead standard for general industry requires the employer to institute a medical surveillance program for all employees who are or may be exposed at or above the AL (30 μg/m^3) for more than 30 days per year. There are three requirements for biological monitoring that are triggered by the current AL (30 μg/m^3):

- At least every 6 months for each employee;
- At least every two months for each employee whose last blood lead test indicated a BLL at or above 40 μg/dL. This frequency shall continue until two consecutive blood lead tests indicate a BLL below 40 μg/dL; and
- At least monthly during the removal period of each employee removed from exposure to lead due to an elevated BLL.

If possible, please discuss and/or submit quantitative estimates of the increases in the number of affected employees and in medical surveillance costs or other pertinent costs if the AL (30 μg/m^3) were decreased. Please specify the AL you assume in your estimation.

(42) Have you upgraded engineering controls to reduce airborne concentrations of lead in your facility? If yes, please describe the controls and whether you observed a subsequent reduction in BLLs. If so, did you monitor to what extent workers' BLLs were reduced following implementation of upgraded controls? Please provide data, if available, on airborne lead concentrations in your facility and on workers' BLLs prior to and following the upgrades. Also provide related initial and annual engineering control costs of upgraded controls, as well as the expected life of the equipment.

(43) Please describe your control strategies to reduce lead surface contamination and the potential for dermal exposure to lead in your facility, such as housekeeping procedures, hygiene areas and practices, and personal protective clothing and equipment (PPE). Please describe such controls, their costs, and explain how well they work and why. To what extent were you able to lower the surface levels of lead? Did you see a subsequent reduction in employee BLLs? Please provide supporting data, if available.

Personal Protective Clothing and Equipment (PPE)

Employers are required to provide work clothing and equipment if an employee is exposed to lead above the PEL or where the possibility of skin or eye irritation exists.

(44) Do you provide PPE in your workplace, including equipment providing respiratory protection? If yes, has it reduced BLLs in your workers? Please describe the type of PPE that you provide.

(45) Does your company have triggers for PPE that are different from requirements under OSHA's lead standards? Please describe the triggers used for providing PPE.

(46) If your firm purchases clothing and equipment to protect employees from lead exposure, please estimate the PPE costs necessary to comply with the current OSHA lead standard. Please give costs on a per employee basis and at an aggregated level, if available.

(47) Have you upgraded PPE to reduce worker exposure to lead? If yes, please describe the controls and whether you observed a subsequent reduction in BLLs. If so, to what extent were workers' BLLs reduced following implementation of upgraded PPE, if applicable? Please provide data, if available.

Housekeeping

OSHA's lead standards contain a housekeeping provision that requires employers to keep surfaces as free as practicable from lead, encourages the use of vacuuming to clean surfaces, limits the use of dry sweeping and shoveling, and prohibits using compressed air to clean surfaces. Some variation exists between the housekeeping provisions for general industry and construction.

(48) Do you have housekeeping procedures? If yes, please describe.

(49) Does your company have cleaning criteria specific to surfaces? This may include a schedule for cleaning and periodic surface cleanliness measurements, specific types of cleaning practices and activities, or other activities associated with surface decontamination.

(50) What are your current housekeeping costs to comply with the OSHA lead standard? Please provide the amount of time allocated for housekeeping costs calculated on an hourly basis.

Hygiene Facilities and Practices

OSHA's lead standards contain hygiene facilities and practices provisions that require employers to provide showers, change rooms, and lunchrooms when workers are exposed to lead above the PEL without regard to the use of respirators. The employer must also ensure that food or beverage is not present or consumed, tobacco products are not present or used, and cosmetics are not applied in areas where workers are exposed above the PEL. Some variation exists between the hygiene facilities and practices provisions for general industry and construction.

(51) Have you provided hygiene facilities or used hygiene practices beyond the requirements of OSHA's lead standards? This may include more frequent hand washing breaks or providing access and time for showers at exposures below the PEL. Please describe how your practices differ from requirements in OSHA's lead standards.

(52) What are your current costs to comply with the hygiene provisions of OSHA's lead standards? Please provide the amount of time allocated for hygiene costs calculated on an hourly basis.

BLLs and Lead Dust Contamination

Some federal agencies, such as the U.S. Department of Housing and Urban Development (HUD) and the EPA, have established lead dust hazard action levels for surfaces (HUD, 2012; EPA 2001). OSHA is interested in

information on using lead dust hazard surface measurements and any observed correlation between surface lead dust levels and elevated BLLs.

(53) Have you taken lead dust surface measurements in your work environment? If so, what are your procedures and current costs for this testing? Please specify the labor and equipment costs for the testing. Have you experienced any impediments or limitations when using wipe sampling to identify surface contamination with lead? What can be done to overcome these barriers?

(54) If you have taken lead dust surface measurements, are they qualitative (presence of lead only) or quantitative? If quantitative, do you use lead dust hazard levels established by HUD and EPA? Please provide any data you have on quantitative surface contamination measurements in your work environment.

(55) Have you evaluated lead surface contamination to investigate elevated employee BLLs in areas where airborne lead exposure was below the PEL? If yes, what were your findings?

(56) Have you taken wipe samples of skin or clothing to identify lead contamination? If yes, what were your findings?

(57) Have you found any correlation between BLLs and lead surface contamination, particularly when airborne exposures are below the PEL?

Impact on Small Business Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), OSHA is required to assess the impact of proposed and final rules on small entities. OSHA requests that members of the small business community, or other parties familiar with regulation of small business, address any special circumstances facing small firms in controlling occupational exposure to lead.

(58) How many and what kinds of small businesses or other small entities in your industry could be affected by lower protective BLL triggers in the OSHA lead standard for general industry? Describe any such effects.

(59) How many and what kinds of small businesses or other small entities in your industry could be affected by lower BLL triggers in the OSHA lead standard for construction? Describe any such effects.

(60) Are there special issues or reasons that lower BLL triggers are more difficult or costlier to implement in small firms? Please describe.

(61) Are there any reasons why benefits from reducing worker BLLs would be different in small firms than in larger firms? With regard to potential impacts on small firms, please describe specific concerns that OSHA should address and any alternatives that might serve to minimize these impacts while meeting the requirements of the OSH Act.

Authority and Signature

Douglas Parker, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC, 20210, authorized the preparation of this document pursuant to the following authorities: sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), Secretary's Order 8–2020 (Sept. 18, 2020), and 29 CFR part 1911.

Signed at Washington, DC, on June 21, 2022.

Douglas L. Parker,

Assistant Secretary of Labor for Occupational Safety and Health.

References

Abt Associates (Abt). (2021). Revised Number of BLL Cases and Firms. Memorandum. Abt Associates, Division of Health and Environment. August 9, 2021.

Adult Blood Lead Epidemiology and Surveillance (ABLES). (2019). Elevated Blood Lead Levels (BLL) among Employed Adults—United States, 2016.

Adult Blood Lead Epidemiology and Surveillance (ABLES). (2020). Tables provided by Rebecca Tsai (NIOSH) to Matt LaPenta (Abt Associates).

Adult Blood Lead Epidemiology and Surveillance (ABLES). (2021). BLL Reference Guide. Retrieved from: *https://www.cdc.gov/niosh/topics/ables/ReferenceBloodLevelsforAdults.html.* Accessed on October 7, 2021.

Agency for Toxic Substance and Disease Registry (ASTDR). (2007). Toxicological Profile for Lead. *http://www.atsdr.cdc.gov/ToxProfiles/tp13.pdf.* Accessed on November 10, 2020.

Agency for Toxic Substance and Disease Registry (ASTDR). (2020). Toxicological Profile for Lead. Retrieved from: *http://www.atsdr.cdc.gov/ToxProfiles/tp13.pdf.* Accessed on November 10, 2020.

American College of Government Industrial Hygienists (ACGIH). (2013). Threshold limit values for chemical substances and physical agents and biological exposure indices. American Conference of Governmental Industrial Hygienists, Cincinnati, OH.

American College of Occupational and Environmental Medicine (ACOEM). (2016). Workplace Lead Exposure: ACOEM Position Statement. JOEM. 58(12): e371–374.

Association of Occupational and Environmental Clinics (AOEC). (2007). Medical Management Guidelines for Lead-Exposed Adults. Retrieved from: *http://www.aoec.org/documents/positions/MMG_FINAL.pdf.* Accessed on November 10, 2020.

California Department of Public Health (CDPH). (2009). Medical Guidelines for the Lead-Exposed Worker. Retrieved from: *http://www.cdph.ca.gov/Programs/CCDPHP/DEODC/OHB/OLPPP/CDPH%20Document%20Library/medgdln.pdf.* Accessed on November 10, 2020.

California Department of Public Health (CDPH). (2010). Summary of CDPH Proposed Changes to the General Industry Lead Standard. Retrieved from *https://www.cdph.ca.gov/Programs/CCDPHP/DEODC/OHB/OLPPP/CDPH%20Document%20Library/LeadStdRecsSummary.pdf.* Accessed on July 14, 2021.

California Department of Public Health (CDPH). (2011). Background to OLPPP's Proposed Changes to the Lead in Construction Standard. Retrieved from: *https://www.cdph.ca.gov/Programs/CCDPHP/DEODC/OHB/OLPPP/CDPH%20Document%20Library/LICStdRecsSummary.pdf.* Accessed on July 14, 2021.

California Department of Public Health (CDPH). (2013). Occupational Lead Poisoning Prevention Program (OLPPP). Retrieved from: *https://www.cdph.ca.gov/Programs/CCDPHP/DEODC/OHB/OLPPP/Pages/OLPPP.aspx.* Accessed on November 10, 2020.

California Department of Public Health (CDPH). (2020a). Table 1. Number of California Workers Tested in 2015–2018, by BLL Threshold and Industry.

California Department of Public Health (CDPH). (2020b). Table 2. Number of California Employers Testing BLLs from 2015–2018, by BLL Threshold and Industry.

Centers for Disease Control and Prevention (CDC). (1982.) Centers for Disease Control and Prevention (CDC). (1982, March 19). Current Trends Blood-Lead Levels in U.S. Population. MMWR. Morbidity and Mortality Weekly Reports. Retrieved from: *https://www.cdc.gov/mmwr/preview/mmwrhtml/00000225.htm.* Accessed on July 14, 2021.

Centers for Disease Control and Prevention, National Notifiable Diseases Surveillance system (NNDSS). (2016). Lead, Elevated Blood Levels, 2016 Case Definition. Retrieved from: *https://ndc.services.cdc.gov/case-definitions/lead-elevated-blood-levels-2016/.* Accessed on November 10, 2020.

Council on State and Territorial Epidemiologists (CSTE). (2015). Public Health Reporting and National Notification for Elevated Blood Lead Levels. 15–EH–01.

Environmental Protection Agency (U.S. EPA). (2013). Final Report: Integrated Science Assessment for Lead. U.S. Environmental Protection Agency, Washington, DC, EPA/600/R–10/075F, 2013. Retrieved from: *https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=255721.* Accessed November 23, 2021.

Grandjean P, Jorgensen PJ, Viskum S. (1991). Temporal and inter-individual variation

in erythrocyte zinc-protoporphyrin in lead exposed workers. Br J Ind Med. 94: 111–115.
Hu H, Shih R, Rothenberg S, Schwartz BS. (2007). The Epidemiology of Lead Toxicity in Adults: Measuring Dose and Consideration of Other Methodologic Issues. Environ Health Perspect. 115: 455–462.
Kosnett MJ, Wedeen RP, Rothenberg SJ, Hipkins KL, Materna BL, Schwartz BS, Hu H, Woolf A. (2007). Recommendations for medical management of adult lead exposure. Environ Health Perspect. 115: 463–471.
Martin CJ, Werntz CL, Ducatman AM. (2004). The interpretation of zinc protoporphyrin changes in lead intoxication: a case report and review of the literature. Occup Med. 54 (8): 587–591.
Michigan Occupational and Environmental Medicine Association (MOEMA). (2019). MOEMA Update, Volume 19, Issue 1. Retrieved from: *http://www.moema.org/files/MOEMA_UPDATE_SUMMER_2019.pdf.*
National Institute for Occupational Safety and Health (NIOSH). (1995). Report to Congress on Workers' Home Contamination Study Conducted Under the Workers' Family Protection Act (29 U.S.C. 671a). Retrieved from: *https://www.cdc.gov/niosh/docs/95-123/default.html.* Accessed on November 23, 2021.
National Institute for Occupational Safety and Health (NIOSH). (2016). ABLES Data Summaries (2016). Retrieved from: *https://www.cdc.gov/niosh/topics/ables/data.html.* Accessed on November 10, 2020.
National Institute for Occupational Safety and Health (NIOSH). (2021). Understanding Blood Lead Levels (February 2021). Retrieved from: *https://www.cdc.gov/niosh/topics/ables/ReferenceBloodLevelsforAdults.html.* Accessed on November 10, 2020.
National Institute for Occupational Safety and Health (NIOSH). (2018). Request for Information About Inorganic Lead (CAS No. 7439–92–1). August 2018. Retrieved from: *https://www.cdc.gov/niosh/docket/review/docket315/pdfs/315-FRN-2018-18019.pdf.* Accessed on July 14, 2021.
National Research Council (NRC). (2013). Potential Health Risks to DOD Firing-Range Personnel from Recurrent Lead Exposure. Committee on Potential Health Risks from Recurrent Lead Exposure of DOD Firing Range Personnel Committee on Toxicology Board on Environmental Studies and Toxicology Division on Earth and Life Studies; National Research Council of the National Academies. The National Academies Press, Washington, DC.
National Toxicology Program (NTP). (2012). NTP Monograph: Health effects of low-level lead. Retrieved from: *https://ntp.niehs.nih.gov/ntp/ohat/lead/final/monographhealtheffectslowlevellead_newissn_508.pdf.* Accessed on November 10, 2020.
Occupational Safety and Health Administration (OSHA). (2007). Regulatory Review of 29 CFR 1926.62 lead in Construction. August 2007. Retrieved from: *https://www.osha.gov/dea/lookback/lead-construction-review.html.* Accessed on November 10, 2020.
Occupational Safety and Health Administration (OSHA). (2008). OSHA Instruction, National Emphasis Program—Lead. Directive number CPL 03–00–009. August 14, 2008. Retrieved from: *https://www.osha.gov/sites/default/files/enforcement/directives/CPL_03-00-0009.pdf.* Accessed on November 10, 2020.
Occupational Safety and Health Administration (OSHA). (2013). Memorandum. Expanded Targeting of Establishments Under the Lead NEP. November 2013. Retrieved from: *https://www.osha.gov/laws-regs/standardinterpretations/2013-11-25.* Accessed on July 14, 2021.
Occupational Safety and Health Administration (OSHA). (2018). Memorandum. [De Minimis] Violation Notices: Blood Laboratory Proficiency Testing and Approval. Retrieved from: *https://www.osha.gov/laws-regs/standardinterpretations/2018-10-01.* Accessed on July 14, 2021.
Occupational Safety and Health Administration (OSHA). (2020a). Lead Exposure—Table 2—Industry Group Profile (Subcategory) OSHA Information System (OIS) Personal Sampling Data for Lead (2014–2018). Salt Lake Technical Center. Retrieved from: *https://www.osha.gov/lead/industry-group-profile.* Accessed on November 10, 2020.
Occupational Safety and Health Administration (OSHA). (2020b). OSHA Enforcement Data, Inspection. Retrieved from: *https://enforcedata.dol.gov/views/data_summary.php.* Accessed on April 3, 2020.
Occupational Safety and Health Administration (OSHA). (2020c). OSHA Enforcement Data, Violation. Retrieved from: *https://enforcedata.dol.gov/views/data_summary.php.* Accessed on April 3, 2020.
Office of Environmental Health Hazard Assessment (OEHHA). (2014). California Environmental Protection Agency; (2014). Estimating Workplace Air and Worker Blood Lead Concentration using an Updated Physiologically-based Pharmacokinetic (PBPK) Model. Retrieved from: *https://oehha.ca.gov/air/document/oehha-presentation-pbpk-model-blood-lead-and-worker-exposure.* Accessed on July 12, 2021.
Payne S, et al. (2017). Blood Lead Levels in California Workers: Data Reported to the Occupational Blood Lead Registry, 2012–2014. Richmond, CA, California Department of Public Health, Occupational Health Branch.
Schwartz BS, Hu H. (2007). Adult lead exposure: time for change. Environ Health Perspect. 115(3): 451–454.
Shih RA, Hu H, Weisskopf MG, Schwartz BS. (2007). Environ Health Perspect. 115(3): 483–492.
U.S. Census Bureau, 2017, Statistics of US Businesses, Program Glossary. Available at: *https://www.census.gov/programs-surveys/susb/about/glossary.html.*
U.S. Department of Defense (DOD). (2018.) DoD 6055.05–M. Occupational Medical Examinations and Surveillance Manual, Incorporating Change 3, August 31, 2018.
U.S. Department of Health and Human Services (HHS). (2022). Fourth national report on human exposure to environmental chemicals, updated tables, March 2022, volume one. Retrieved from: *https://www.cdc.gov/exposurereport/data_tables.html.* Accessed April 25, 2022.
U.S. Department of Housing and Urban Development (HUD). (2012). Guidelines for the Evaluation and Control of Lead-Based Paint Hazards in Housing (2012 Edition). Retrieved from: *https://www.hud.gov/program_offices/healthy_homes/lbp/hudguidelines.* Accessed on November 10, 2020.

Appendix A

TABLE 1—SUMMARY OF ANNUAL NUMBER OF FIRMS WITH BLL TESTS AND CASES [1]

NAICS	NAICS description	Estimated number of firms where employees receive BLL tests	Estimated number of firms with BLL cases			
			BLL ≥5	BLL ≥10	BLL ≥25	BLL ≥ medical removal BLL [2]
1151	Support Activities for Crop Production	2	1	0	0	0
2122	Metal Ore Mining	466	78	36	11	0
2123	Nonmetallic Mineral Mining and Quarrying	17	2	0	0	0
2131	Support Activities for Mining	35	5	0	0	0
2211	Electric Power Generation, Transmission and Distribution.	25	22	22	10	0
2212	Natural Gas Distribution	138	19	11	2	0

TABLE 1—SUMMARY OF ANNUAL NUMBER OF FIRMS WITH BLL TESTS AND CASES [1]—Continued

NAICS	NAICS description	Estimated number of firms where employees receive BLL tests	Estimated number of firms with BLL cases			
			BLL ≥5	BLL ≥10	BLL ≥25	BLL ≥ medical removal BLL [2]
2213	Water, Sewage and Other Systems	9	9	0	0	0
2361	Residential Building Construction	769	145	83	37	2
2362	Nonresidential Building Construction	864	323	204	67	9
2371	Utility System Construction	87	50	36	10	1
2373	Highway, Street, and Bridge Construction	386	136	91	43	4
2379	Other Heavy and Civil Engineering Construction.	51	10	10	8	1
2381	Foundation, Structure, and Building Exterior Contractors.	251	171	95	11	1
2382	Building Equipment Contractors	488	132	58	31	4
2383	Building Finishing Contractors	2,746	655	452	199	34
2389	Other Specialty Trade Contractors	1,305	354	227	47	9
2399	Construction (Specific industry unknown)	516	86	25	25	0
3231	Printing and Related Support Activities	146	20	11	2	0
3241	Petroleum and Coal Products Manufacturing	11	11	0	0	0
3251	Basic Chemical Manufacturing	42	20	11	2	0
3252	Resin, Synthetic Rubber, and Artificial and Synthetic Fibers and Filaments Manufacturing.	175	25	13	3	0
3255	Paint, Coating, and Adhesive Manufacturing	38	21	12	2	0
3259	Other Chemical Product and Preparation Manufacturing.	158	22	12	2	0
3271	Clay Product and Refractory Manufacturing	99	50	27	5	0
3272	Glass and Glass Product Manufacturing	5,156	715	398	113	2
3279	Other Nonmetallic Mineral Product Manufacturing.	12	2	0	0	0
3311	Iron and Steel Mills and Ferroalloy Manufacturing.	99	13	13	13	1
3312	Steel Product Manufacturing from Purchased Steel.	184	26	14	3	0
3314	Nonferrous Metal (except Aluminum) Production and Processing.	1,431	224	189	187	13
3315	Foundries	1,103	152	102	28	1
3323	Architectural and Structural Metals Manufacturing.	994	142	91	44	2
3324	Boiler, Tank, and Shipping Container Manufacturing.	261	38	23	7	0
3325	Hardware Manufacturing	166	23	13	2	0
3327	Machine Shops; Turned Product; and Screw, Nut, and Bolt Manufacturing.	53	15	15	14	0
3328	Coating, Engraving, Heat Treating, and Allied Activities.	256	39	22	10	0
3329	Other Fabricated Metal Product Manufacturing	1,100	187	154	46	1
3333	Commercial and Service Industry Machinery Manufacturing.	133	19	10	2	0
3336	Engine, Turbine, and Power Transmission Equipment Manufacturing.	17	17	0	0	0
3339	Other General Purpose Machinery Manufacturing.	65	9	9	2	0
3341	Computer and Peripheral Equipment Manufacturing.	6	1	0	0	0
3342	Communications Equipment Manufacturing	146	31	17	3	0
3343	Audio and Video Equipment Manufacturing	4	0	0	0	0
3344	Semiconductor and Other Electronic Component Manufacturing.	323	37	25	9	1
3345	Navigational, Measuring, Electromedical, and Control Instruments Manufacturing.	394	72	37	11	0
3359	Other Electrical Equipment and Component Manufacturing.	851	165	136	136	24
3363	Motor Vehicle Parts Manufacturing	994	142	89	33	2
3364	Aerospace Product and Parts Manufacturing	427	96	40	21	1
3366	Ship and Boat Building	23	23	13	13	0
3369	Other Transportation Equipment Manufacturing	9	8	0	0	0
3399	Other Miscellaneous Manufacturing	296	53	53	12	0
4231	Motor Vehicle and Motor Vehicle Parts and Supplies Merchant Wholesalers.	305	57	31	6	0
4236	Household Appliances and Electrical and Electronic Goods Merchant Wholesalers.	330	46	25	6	0

TABLE 1—SUMMARY OF ANNUAL NUMBER OF FIRMS WITH BLL TESTS AND CASES [1]—Continued

NAICS	NAICS description	Estimated number of firms where employees receive BLL tests	Estimated number of firms with BLL cases			
			BLL ≥5	BLL ≥10	BLL ≥25	BLL ≥ medical removal BLL [2]
4237	Hardware, and Plumbing and Heating Equipment and Supplies Merchant Wholesalers.	130	18	10	2	0
4238	Machinery, Equipment, and Supplies Merchant Wholesalers.	12	2	0	0	0
4239	Miscellaneous Durable Goods Merchant Wholesalers.	629	141	141	130	3
4244	Grocery and Related Product Merchant Wholesalers.	7	1	0	0	0
4247	Petroleum and Petroleum Products Merchant Wholesalers.	14	2	0	0	0
4413	Automotive Parts, Accessories, and Tire Stores	136	19	10	2	0
4441	Building Material and Supplies Dealers	134	19	10	2	0
4451	Grocery Stores	8	1	0	0	0
4483	Jewelry, Luggage, and Leather Goods Stores	125	18	10	2	0
4511	Sporting Goods, Hobby, and Musical Instrument Stores.	780	109	60	11	0
4821	Rail Transportation	8	8	8	2	0
4841	General Freight Trucking	13	13	0	0	0
4842	Specialized Freight Trucking	12	3	0	0	0
4851	Urban Transit Systems	3	3	3	2	0
4881	Support Activities for Air Transportation	21	21	21	12	0
4883	Support Activities for Water Transportation	306	45	25	6	0
4884	Support Activities for Road Transportation	183	11	10	3	0
4911	Postal Service	0	0	0	0	0
4921	Couriers and Express Delivery Services	8	1	0	0	0
5111	Newspaper, Periodical, Book, and Directory Publishers.	131	18	10	2	0
5173	Wired and Wireless Telecommunications Carriers.	10	1	0	0	0
5182	Data Processing, Hosting, and Related Services.	0	0	0	0	0
5211	Monetary Authorities-Central Bank	131	18	10	2	0
5242	Agencies, Brokerages, and Other Insurance Related Activities.	10	3	0	0	0
5311	Lessors of Real Estate	7	4	0	0	0
5313	Activities Related to Real Estate	231	32	18	3	0
5323	General Rental Centers	53	19	10	4	0
5324	Commercial and Industrial Machinery and Equipment Rental and Leasing.	113	16	9	2	0
5413	Architectural, Engineering, and Related Services.	218	88	65	12	0
5415	Computer Systems Design and Related Services.	121	17	9	2	0
5416	Management, Scientific, and Technical Consulting Services.	153	53	19	7	0
5417	Scientific Research and Development Services	12	12	8	2	0
5419	Other Professional, Scientific, and Technical Services.	125	18	10	2	0
5611	Office Administrative Services	118	17	9	2	0
5613	Employment Services	119	45	34	10	0
5614	Business Support Services	12	2	0	0	0
5616	Investigation and Security Services	395	66	36	7	0
5617	Services to Buildings and Dwellings	127	18	10	2	0
5621	Waste Collection	102	35	19	4	0
5622	Waste Treatment and Disposal	39	28	22	6	0
5629	Remediation and Other Waste Management Services.	1,663	739	494	190	4
6111	Elementary and Secondary Schools	4	3	3	2	0
6112	Junior Colleges	146	20	11	2	0
6113	Colleges, Universities, and Professional Schools.	11	8	0	0	0
6115	Technical and Trade Schools	714	100	46	10	0
6116	Other Schools and Instruction	745	111	61	19	0
6211	Offices of Physicians	9	9	0	0	0
6214	Outpatient Care Centers	9	5	0	0	0
6215	Medical and Diagnostic Laboratories	9	9	0	0	0
6219	Other Ambulatory Health Care Services	9	4	4	4	0
6221	General Medical and Surgical Hospitals	10	4	0	0	0

TABLE 1—SUMMARY OF ANNUAL NUMBER OF FIRMS WITH BLL TESTS AND CASES [1]—Continued

NAICS	NAICS description	Estimated number of firms where employees receive BLL tests	Estimated number of firms with BLL cases			
			BLL ≥5	BLL ≥10	BLL ≥25	BLL ≥ medical removal BLL [2]
6222	Psychiatric and Substance Abuse Hospitals	12	12	0	0	0
6232	Residential Intellectual and Developmental Disability, Mental Health, and Substance Abuse Facilities.	15	15	0	0	0
6241	Individual and Family Services	51	18	10	2	0
6243	Vocational Rehabilitation Services	10	1	0	0	0
7115	Independent Artists, Writers, and Performers ...	3	1	0	0	0
7121	Museums, Historical Sites, and Similar Institutions.	309	50	30	21	0
7131	Amusement Parks and Arcades	3	3	0	0	0
7139	Other Amusement and Recreation Industries ...	6,656	1024	619	205	9
8111	Automotive Repair and Maintenance	3,333	553	310	72	1
8112	Electronic and Precision Equipment Repair and Maintenance.	29	17	17	11	0
8113	Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance.	79	14	10	6	0
8114	Personal and Household Goods Repair and Maintenance.	953	133	71	34	1
8122	Death Care Services	145	20	11	2	0
8131	Religious Organizations	12	3	0	0	0
8139	Business, Professional, Labor, Political, and Similar Organizations.	488	72	50	28	1
9211	Executive, Legislative, and Other General Government Support.	0	0	0	0	0
9221	Justice, Public Order, and Safety Activities	0	0	0	0	0
9231	Administration of Human Resource Programs ..	0	0	0	0	0
9241	Administration of Environmental Quality Programs.	0	0	0	0	0
9251	Administration of Housing Programs, Urban Planning, and Community Development.	0	0	0	0	0
9261	Administration of Economic Programs	0	0	0	0	0
9281	National Security and International Affairs	0	0	0	0	0
Total		44,144	8,611	5,302	2,087	137

[1] The Census Bureau defines an establishment as a single physical location at which business is conducted or services or industrial operations are performed. The Census Bureau defines a business firm or entity as a business organization consisting of one or more domestic establishments in the same state and industry that are specified under common ownership or control. The firm and the establishment are the same for single-establishment firms. For each multi-establishment firm, establishments in the same industry within a state will be counted as one firm; the firm employment and annual payroll are summed from the associated establishments.

[2] Medical removal levels are BLL ≥50 μg/dL in Construction (NAICS 23) and BLL ≥60 μg/dL in General Industry.

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BILLING CODE 4510–26–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2021–0772; FRL–9889–01–R6]

Air Plan Approval; New Mexico; Interstate Transport Requirements for 2010 Nitrogen Dioxide National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve the State Implementation Plan (SIP) revision submitted by the State of New Mexico, through New Mexico Environment Department (NMED) dated June 25, 2021, for the purpose of addressing the Clean Air Act (CAA or ''Act'') ''good neighbor'' interstate transport (prongs 1 and 2) infrastructure SIP requirements for the 2010 1-hour Nitrogen Dioxide (NO_2) National Ambient Air Quality Standard (NAAQS). The CAA requires that each state adopt and submit a SIP for the implementation, maintenance, and enforcement of each NAAQS promulgated by the EPA, commonly referred to as an ''infrastructure SIP.'' Specifically, the EPA is proposing to approve New Mexico's June 25, 2021, SIP revision addressing prongs 1 and 2 to ensure that air emissions in the State do not significantly contribute to nonattainment or interfere with maintenance of the 2010 1-hour NO_2 NAAQS in any other state. The EPA is proposing to approve this action pursuant to section 110 and part D of the CAA and the EPA's regulations.

DATES: Written comments must be received on or before July 28, 2022.

ADDRESSES: Submit your comments, identified by Docket No. EPA–R06–OAR–2021–0772, at *https://www.regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other

information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT SECTION.** For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

Docket: The index to the docket for this action is available electronically at *www.regulations.gov.* While all documents in the docket are listed in the index, some information may not be publicly available due to docket file size restrictions or content (*e.g.,* CBI).

FOR FURTHER INFORMATION CONTACT: Ms. Nevine Salem, EPA Region 6 Office, Infrastructure and Ozone Section, 214–665–7222, *salem.nevine@epa.gov.* The EPA Region 6 office may be closed to the public to reduce the risk of transmitting COVID–19. We encourage the public to submit comments via *https://www.regulations.gov,* as there is a delay in processing mail and no courier or hand deliveries will be accepted. Please call or email the contact listed above if you need alternative access to material indexed but not provided in the docket.

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, we mean the EPA.

I. Background

On January 22, 2010, the EPA established a new 1-hour primary NAAQS for NO_2 at a level of 100 parts per billion (ppb), based on a 3-year average of the 98th percentile of the yearly distribution of 1-hour daily maximum concentrations.[1] *See* 75 FR 6474 (February 9, 2010). This NAAQS is designed to protect against exposure to the entire group of nitrogen oxides (NO_X). NO_2 is the component of greatest concern and is used as the indicator for the larger group of NO_X. Emissions that lead to the formation of NO_2 generally also lead to the formation of other NO_X. Therefore, control measures that reduce NO_2 can generally be expected to reduce population exposures to all gaseous NO_X which may have the co-benefit of reducing the formation of ozone and fine particles both of which pose significant public health threats. For comprehensive information on the 2010 1-hour NO_2 NAAQS, please refer to the February 9, 2010 **Federal Register** action. *See* 75 FR 6474.

Whenever the EPA promulgates a new or revised NAAQS, CAA section 110(a)(1) requires states to submit SIPs meeting the applicable requirements of section 110(a)(2) within 3 years after promulgation of a new or revised NAAQS or within such shorter period as the EPA may prescribe. Section 110(a)(2) requires states to address structural SIP elements such as requirements for monitoring, basic program requirements, and legal authority that are designed to provide for implementation, maintenance, and enforcement of the NAAQS. The EPA refers to the SIP submissions required by these provisions as ''infrastructure SIPs.'' Section 110(a) imposes the obligation upon states to make an infrastructure SIP submission to the EPA for a new or revised NAAQS, but the contents of individual state submissions may vary depending upon the facts and circumstances. This proposed rule pertains to the infrastructure SIP requirements for interstate transport of air pollution. These submissions must meet the various requirements of CAA section 110(a)(2), as applicable.[2]

Section 110(a)(2)(D)(i) of the CAA requires SIPs to include provisions prohibiting any source or other type of emissions activity in one state from emitting any air pollutant in amounts that will contribute significantly to nonattainment, or interfere with maintenance, of the NAAQS, or interfere with measures required to prevent significant deterioration of air quality or to protect visibility in any other state. This proposed rule addresses the two requirements under section 110(a)(2)(D)(i)(I), which we refer to as prong 1 (significant contribution to nonattainment of the NAAQS in any other state) and prong 2 (interference with maintenance of the NAAQS in any other state). The EPA often refers to SIP revisions addressing the requirements of section 110(a)(2)(D)(i)(I) as ''interstate transport SIPs.''

The EPA evaluates each state's interstate transport SIP to see how the state evaluates the transport of air pollution to other states for a given air pollutant; what types of information the state used in its analysis; how that analysis compares with prior EPA rulemakings, modeling, monitoring, and guidance; and what conclusions were drawn by the state. If the EPA concludes that the SIP contains adequate provisions to prohibit sources from emitting air pollutants that significantly contribute to nonattainment, or interfere with maintenance, of a given NAAQS in any other state, we will approve the state's submission with regard to prongs 1 and 2 of CAA section 110(a)(2)(D)(i)(I).

II. State's Submittal

On March 12, 2014, the New Mexico Environment Department (NMED) submitted its Infrastructure SIP to the EPA for the revised 2010 1-hour NO_2 standard. At that time, NMED addressed the 2010 NO_2 interstate transport prongs 1 and 2 by referencing the EPA's November 19, 2012 Memorandum [3] which outlined the EPA's intention to abide by the August 21, 2012 decision of the U.S. Court of Appeals for the D.C. Circuit, holding that a SIP cannot be deemed deficient for failing to meet the prong 1 and 2 requirements in Section 110(a)(2)(D)(i) before the EPA quantifies the state's obligation. *EME Homer City Generation, L.P.* v. *EPA,* 696 F.3d 7 (D.C. Cir. 2012). In the March 2014 submittal, the state stated that the EPA had not yet quantified New Mexico's interstate transport obligation under the 2010 NO_2 and therefore New Mexico's infrastructure SIP was adequate for section 110(a)(2)(D)(i)(I).

On April 29, 2014, the U.S. Supreme Court reversed and remanded the D.C. Circuit's EME Homer City ruling and upheld the EPA's approach in the Cross-State Air Pollution Rule. *EPA* v. *EME Homer City Generation, L.P.,* 572 U.S. 489 (2014). As a result of the Supreme Court reversal, each state was again required to address the interstate transport requirements of 110(a)(2)(D)(i) regardless of whether the EPA had quantified the state's obligation. In accordance with the Supreme Court's

[1] Subsequently, after careful consideration of the scientific evidence and information available, on April 18, 2018, EPA published a final action to retain the current NO_2 standard at the 2010 level of 100 ppb. This action was taken after review of the full body of available scientific evidence and information, giving particular weight to the assessment of the evidence in the 2016 NO_X Integrated Science Assessment; analyses and considerations in the Policy Assessment; the advice and recommendations of the Clean Air Scientific Advisory Committee; and public comments. *See* 83 FR 17226 (April 18, 2018).

[2] States were required to submit infrastructure SIPs for the 2010 1-hour NO_2 NAAQS to EPA no later than January 22, 2013.

[3] See ''Next Steps for Pending Redesignation Requests and State Implementation Plan Actions Affected by the Recent Court Decision Vacating the 2011 Cross-State Air Pollution Rule,'' signed by EPA Assistant Administrator Gina McCarthy November 19, 2012. This memorandum is in the docket for this action.

decision, on June 25, 2021, the state of New Mexico supplemented its 2010 NO_2 infrastructure SIP to address interstate transport prongs 1 and 2 of Section 110(a)(2)(D)(i), the submission supplements the State's prior 2014 interstate transport SIP for the NO_2 NAAQS.

III. The EPA's Evaluation

A. Evaluation for the 2010 1-Hour NO_2

1. The EPA's General Approach To Evaluating the 2010 NO_2

Unlike certain other NAAQS like ozone and $PM_{2.5}$, the EPA has not developed a recommended approach for states to use when addressing prongs 1 and 2 for the 2010 NO_2 NAAQS. Following promulgation of the 2010 NO_2 NAAQS, the EPA designated all areas of the United States as ''unclassifiable/attainment'' for this NAAQS because monitors throughout the country had indicated no violations of the NAAQS from 2008–2010.[4] 77 FR 9532 (February 17, 2012). Additionally, no violations occurred at any monitor in the country in the most recent available design value period of 2018–2020.[5] For these reasons, 110(a)(2)(D)(i)(I) demonstrations for states have been relatively straightforward because the EPA has not identified areas in any state to which emissions from another state would likely contribute significantly to nonattainment or interfere with maintenance.

2. State's Submission

In New Mexico's June 25, 2021, SIP revision, NMED concluded that its SIP adequately addresses prong 1 and 2 with respect to the 2010 1-hour NO_2 NAAQS. NMED provided the following reasons for its determinations: (1) all areas in the United States are designated as unclassifiable/attainment for the 2010 1-hour NO_2 NAAQS; (2) there are SIP-approved and state-only regulations that directly or indirectly control NO_2 emissions.

3. The EPA's Analysis

In addition to the information provided in the SIP, the EPA notes that the highest monitored valid NO_2 design values in each state bordering New Mexico are well below the NAAQS (see Table 1, below), as are the maximum single year 98th percentile values from each neighboring state between 2018–2020 (see Table 2, below). These facts further support the State's assertion that significant contribution to nonattainment or interference with maintenance of the NO_2 NAAQS from New Mexico is unlikely.

TABLE 1—1-HOUR NO_2 DESIGN VALUES IN NEW MEXICO AND NEIGHBORING STATES

State	2018–2020 NO_2 design value (ppb)
New Mexico	38
Arizona	49
Colorado	52
Oklahoma	26
Texas	32

TABLE 2—MAX 98TH PERCENTILE NO_2 CONCENTRATION IN NEW MEXICO AND NEIGHBORING STATES

State	Year	Highest single year 98th percentile value from 2018–2020 (ppb)
New Mexico	2020	49
Arizona	2018	62
Colorado	2020	71
Oklahoma	2018	41
Texas	2018	69

With respect to prong 2 (interference with maintenance), specifically, in addition to the lack of areas violating the NO_2 NAAQS, there are also no areas in neighboring states approaching a violation of the 2010 NO_2 NAAQS (*i.e.,* 100 ppb) which might therefore be expected to have difficulty maintaining the standard. With respect to both prongs, we also note that there are no areas elsewhere in the United States approaching a violation of the 2010 NO_2 NAAQS.

NMED notified the public with the publication of the notice in both print and online versions of the Albuquerque Journal (in English and Spanish). The public notice provided opportunity for comment and public hearing. NMED did not receive any public comment and no request for public hearing was received. A copy of the New Mexico SIP revision submittal is available online at *www.regulations.gov,* Docket number EPA–R06–OAR–2021–0772

IV. Proposed Action

Based on our review of New Mexico's June 25, 2021, SIP revision submission, and our analysis of additional relevant information, we propose to determine that emissions from New Mexico will not significantly contribute to nonattainment or interfere with the maintenance of the 2010 NO_2 NAAQS in any other state. Accordingly, we propose to approve the June 25, 2021, New Mexico SIP submission as satisfying the requirements of CAA section 110(a)(2)(D)(i)(I) for the 2010 1-hour NO_2 NAAQS interstate transport prongs 1 and 2. The EPA is soliciting public comments on this proposed action and will consider public comments received during the comment period.

[4] For comparison with the 2010 NO_2 1-hour NAAQS, a three-year design value is used. 40 CFR 50.11(f).

[5] See *https://www.epa.gov/air-trends/air-quality-design-values#report.* As this report indicates, no regulatory monitor in the U.S. recorded a design value above 80 ppb for the 2018–2020 design value period.

V. Environmental Justice Considerations

Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, Feb. 16, 1994) directs federal agencies to identify and address ''disproportionately high and adverse human health or environmental effects'' of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. The EPA defines environmental justice (EJ) as ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.'' The EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.'' [6] The EPA is providing additional analysis of environmental justice associated with this action for the purpose of providing information to the public.

The EPA reviewed demographic data, which provides an assessment of individual demographic groups of the populations within New Mexico.[7] The EPA then compared the data to the national average for each of the demographic groups. The results of the demographic analysis indicate that, for populations within New Mexico, the percentage of people of color (persons who reported their race as a category other than White alone (not Hispanic or Latino)) is significantly higher than the national average (63.8 percent versus 40 percent). Within people of color, the percentage of the population that is Hispanic or Latino is higher than the national averages (49.3 percent versus 18.5 percent) and the percentage of the population that is American Indian/Alaska Native is also higher than the national average (11.0 percent versus 1.3 percent). The percentage of people living below the poverty level in New Mexico is higher than the national average (16.8 percent versus 11.4 percent). The percentage of people over 25 with a high school diploma in New Mexico is slightly below the national average (86.5 percent versus 88.5 percent), similarly, for the percentage with a bachelor's degree or higher education is slightly lower than the national average (28.1 percent versus 32.9 percent).

Communities in close proximity to and/or downwind of industrial sources may be subject to disproportionate environmental impacts of NO_2 emissions. Short- and/or long-term exposure to elevated concentrations of NO_2 may contribute to the development of asthma and may potentially increase susceptibility to respiratory infections. People with asthma, as well as children and the elderly are generally at greater risk for the health effects of NO_2.[8] However, there are no areas in New Mexico or nationwide that show problems attaining or maintaining air quality with regard to NO_2 emissions that may contribute to environmental and health impacts on all populations including minority and low-income population. In addition, the national average of NO_2 concentrations have decreased substantially over the years.[9] We therefore conclude that this proposed rule will not have or lead to disproportionately high or adverse human health or environmental effects on communities with environmental justice concerns.

VI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Ozone, Reporting and record keeping requirements, Volatile organic compounds.

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

Dated: June 22, 2022.

Earthea Nance,

Regional Administrator, Region 6.

[FR Doc. 2022–13725 Filed 6–27–22; 8:45 am]

BILLING CODE 6560–50–P

[6] *https://www.epa.gov/environmentaljustice/learn-about-environmental-justice.*

[7] *See* the United States Census Bureau's QuickFacts on New Mexico at *https://www.census.gov/quickfacts/fact/table/NM,US/PST045221.*

[8] *https://www.epa.gov/air-quality-management-process/managing-air-quality-human-health-environmental-and-economic#what* (URL dated 03/16/2022).

[9] See *https://www.epa.gov/air-trends/nitrogen-dioxide-trends.*

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 220617–0138]

RIN 0648–BL02

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; Red Snapper Data Calibrations and Harvest Levels

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to implement management measures described in two framework actions under the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP), as prepared by the Gulf of Mexico (Gulf) Fishery Management Council (Council). If implemented, this proposed rule would modify the state-specific red snapper private angling components annual catch limits (ACLs) to reflect each state's monitoring program. In addition, this proposed rule would modify commercial and recreational sector and recreational component red snapper ACLs and annual catch targets (ACTs) in the Gulf exclusive economic zone (EEZ). The purpose of this proposed rule is to calibrate Gulf red snapper state private angling component ACLs to reduce the likelihood of overfishing, to increase the Gulf red snapper ACLs and ACTs consistent with updated scientific information, and to continue to achieve optimum yield (OY) for the stock.

DATES: Written comments must be received on or before July 28, 2022.

ADDRESSES: You may submit comments on the proposed rule, identified by ''NOAA–NMFS–2022–0028'' by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and enter ''NOAA–NMFS–2022–0028'', in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Dan Luers, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Electronic copies of the framework actions, which include environmental assessments, regulatory impact reviews, and Regulatory Flexibility Act (RFA) analyses, may be obtained from the Southeast Regional Office website at *https://www.fisheries.noaa.gov/action/red-snapper-data-calibrations-and-catch-limit-modifications.*

FOR FURTHER INFORMATION CONTACT: Dan Luers, Southeast Regional Office, NMFS, telephone: 727–824–5305, email: *daniel.luers@noaa.gov.*

SUPPLEMENTARY INFORMATION: The Gulf reef fish fishery, which includes red snapper, is managed under the FMP. The FMP was prepared by the Council and is implemented by NMFS through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Steven Act).

Unless otherwise noted, all weights in this proposed rule are in round weight.

This proposed rule would implement management measures for both the Gulf of Mexico Red Snapper Recreational Data Calibration and Recreational Catch Limits Framework Action (Calibration Framework) and the Modification of Annual Catch Limits for Gulf of Mexico Red Snapper Framework Action (Catch Limits Framework). Briefly, the Calibration Framework would modify the state-specific red snapper private angling component ACLs using the calibration ratios developed by NMFS' Office of Science and Technology and the Gulf states. The Catch Limits Framework would increase the red snapper overfishing limit (OFL), acceptable biological catch (ABC), ACLs, and ACTs consistent with the red snapper interim analyses and recommendations from the Council's Scientific and Statistical Committee (SSC). These two framework actions are combined in this single proposed rule because both actions adjust the red snapper catch limits.

Background

The Magnuson-Stevens Act requires NMFS and regional fishery management councils to prevent overfishing and to achieve, on a continuing basis, the OY from federally managed fish stocks to ensure that fishery resources are managed for the greatest overall benefit to the nation, particularly with respect to providing food production and recreational opportunities, and protecting marine ecosystems.

Red snapper in the Gulf EEZ is harvested by both the commercial and recreational sectors. Each sector has its own ACL and associated management measures. The stock ACL is allocated 51 percent to the commercial sector and 49 percent to the recreational sector. These sector allocations were implemented in 1990 through Amendment 1 to the Reef Fish FMP (55 FR 14; January 22, 1990). The stock ACL for red snapper was set at and remains equal to the ABC. In 2015, Amendment 40 to the FMP (80 FR 22422; April 22, 2015) divided the recreational ACL (quota) between the Federal for-hire component (42.3 percent), which includes operators of federally permitted charter vessels and headboats (for-hire vessels), and the private angling component (57.7 percent), which includes private anglers.

In February 2020, NMFS implemented state management of red snapper for the private angling component through Amendments 50 A–F to the FMP (85 FR 6819; February 6, 2020). Through these amendments, each state was allocated a portion of the red snapper private angling component ACL and was delegated the authority to set the private angling fishing season, bag limit, and size limit. These amendments also established an accountability measure that required any overage of a state's ACL to be deducted in the following year (*i.e.,* a payback provision).

The Calibration Framework

The Calibration Framework describes in detail the various data collection programs used to estimate red snapper landings by private anglers. Until recently (2014), NMFS provided the only estimates of private angler red snapper landings in all of the Gulf states, except Texas. Texas anglers have never participated in the NMFS recreational data collection survey. In 2014, Alabama and Louisiana, and in 2015, Florida and Mississippi, implemented state data collection programs to collect this private angler information. Each of these programs is unique and NMFS has observed differences (sometimes substantial) between Federal estimates of recreational catch and each state's own estimate. Specifically, the Alabama and

Mississippi surveys tend to generate much lower landings estimates than the Federal survey.

The current red snapper catch limits (OFL, ABC, ACLs, and ACTs) are based, in part, on private-angling landings estimated using the Federal data collection system, and NMFS uses the estimates from the Federal survey to determine whether landings exceed the total recreational ACL (quota) and the stock OFL. However, each Gulf state manages the harvest by its private anglers using estimates from its own state data collection program. The MRIP-based catch limits for Florida, Alabama, Mississippi, and Louisiana are not directly comparable to the landings estimates generated by each of those states, and the state estimates are not directly comparable to each other. In other words, each state is estimating landings in a different ''currency.'' Therefore, the NMFS Office of Science and Technology (OST) worked with the Gulf States to develop calibration ratios so that each state's catch limit could be converted to the ''currency'' in which each state monitors landings.

The current systems each state uses to manage private angling harvest have resulted in exceeding the total recreational ACL (quota) and the OFL. In 2018 and 2019, the private angling component ACL and recreational ACL were exceeded even though the Federal for-hire component landings did not exceed the for-hire component ACL. In 2019, total red snapper landings exceeded the OFL.

To address this issue, the Council developed the Calibration Framework and selected as preferred the alternative that uses the calibration ratios to adjust each state's ACL into the ''currency'' in which that state monitors landings. These ratios are: Alabama (0.4875); Florida (1.0602); Louisiana (1.06); Mississippi (0.3840); Texas (1.00). The MRIP-based ACLS are multiplied by the ratios to determine the state currency ACLs. The preferred alternative also included an implementation date of January 1, 2023. The Council concluded that this delay in implementation would afford the Gulf states and the NMFS OST an opportunity to resolve the differences in state-specific data collection programs and MRIP–FES (*e.g.,* scale and precision of catch estimates), as recommended by both the Council's SSC (during discussion at several SSC meetings) and a 2021 National Academy of Sciences report to Congress.

In February 2022, NMFS OST and the Gulf states participated in a workshop on the transition to the use of state survey catch data in Gulf of Mexico fisheries. The purpose of the workshop was to agree on the elements of a Gulf State Recreational Catch and Effort Estimation Surveys Transition Plan. When executed, this plan will allow for the full use of state recreational fishing data in NOAA Fisheries' stock assessment and management processes. More information about this workshop can be found at *https://www.fisheries.noaa.gov/event/gulf-state-recreational-catch-and-effort-surveys-transition-workshop.*

The Catch Limits Framework

In 2019, NMFS implemented a framework action that set the current red snapper catch limits (85 FR 6819; February 6, 2020). These catch limits are based on most recent Gulf red snapper Southeast Data, Assessment, and Review stock assessment (SEDAR 52), completed in 2018, and the Council's SSC recommendations. The current red snapper stock OFL is 15.5 million lb (7.0 million kg), the ABC and stock ACL are 15.1 million lb (6.8 million kg). The commercial ACL is 7.701 million lb (3.493 million kg), and the recreational ACL is 7.399 million lb (3.356 million kg). The Federal for-hire component ACL is 3.130 million lb (1.420 million kg) and the private angling component ACL is 4.269 million lb (1.936 million kg). The Federal for-hire component ACT is 2.848 million lb (1.292 million kg) and the private angling component ACT is 3.415 million lb (1.5498 million kg). The commercial sector does not have a sector ACT because it is managed under an individual fishing quota (IFQ) program that effectively constrains landings to the commercial ACL. The 2019 framework also set the Federal for-hire component ACT at 9 percent below its ACL. The for-hire component ACT is in place to reduce the likelihood of exceeding the for-hire ACL, as well as the total recreational ACL. A private angling component ACT is set 20 percent below the private angling ACL, but would only be used if a Gulf state did not have an active delegation under the red snapper state management program.

In 2016, Congress awarded funding to researchers in an effort to independently estimate the population size of red snapper in the Gulf. Commonly known as the ''Great Red Snapper Count'' (GRSC), this project's primary goal was to provide a snapshot of estimate abundance and distribution of age 2 and older red snapper on artificial, natural, and uncharacterized bottom habitat across the northern Gulf through 2019. At its April 2021 meeting, the Council was briefed on the results of the GRSC. The GRSC estimated the abundance of red snapper in the Northern Gulf was approximately three times greater than had been estimated in the previous stock assessment (SEDAR 52).

The Southeast Fisheries Science Center (SEFSC) worked collaboratively with the GRSC investigators to develop a method that could be used to integrate the results of the GRSC into catch limit advice that is currently based on SEDAR 52. The SEFSC developed catch projections using GRSC estimates of abundance to scale projections that initially used abundance estimates from SEDAR 52. The SEFSC also developed catch level projections based on an interim analysis using information from the NMFS Bottom Longline (BLL) survey, which was similar to the approach previously used for Gulf red grouper and gray triggerfish projections. The NMFS BLL survey is an annual survey that can be used to determine long-term trends in the abundance of a stock.

The SSC reviewed both sets of projections at its March 30–April 2, 2021, meeting. The SSC expressed some concerns about using the GRSC findings to recommend catch levels. Specifically, the SSC noted the uncertainty associated with the GRSC biomass estimate, questions about the productivity of the red snapper stock that are raised by the GRSC findings (that the productivity of the stock appears to be lower than previously assumed), and the declining trend observed recently in the NMFS BLL survey. Based on these concerns, and until additional information could be presented related to the SSC's questions about some aspects of the GRSC, the SSC determined that it was appropriate to use the GRSC based interim analysis to recommend the OFL, which would be used determine if overfishing is occurring, but not to recommend the ABC, which constrains the total allowable catch that may be specified by the Council.

For the OFL recommendation, the SSC decided to use the projection based on the abundance of all red snapper over structure (artificial reef, natural reef, and pipeline) and 13 percent of the abundance from the unclassified bottom, and used a 3-year average of the maximum sustainable yield proxy for Gulf red snapper (the mortality corresponding to a 26 percent reduction in the spawning potential ratio from an unfished condition). This OFL for Gulf red snapper is 25.6 million lb (11.6 million kg). With respect to the ABC, the SSC determined that 2020 data should not be used for this interim analysis because of the low sample size and high coefficient of variation for that

data, and recommended that the catch advice be derived from the 5-year average. Based on these selections, the Council's SSC provided an ABC recommendation for Gulf red snapper of 15.4 million lb (7.0 million kg). This recommendation reflects the SSC's determination that the ABC should be considerably more conservative than the OFL, at least until the SSC questions related to the GRSC are more thoroughly explored.

The SSC has reviewed new information related the GRSC on several occasions. At its March 2022 meeting, the SSC made new catch level recommendations based a SEFSC analysis that used updated GRSC information. These new recommendations would decrease the OFL to 18.91 million lb (8.58 million kg) and increase the ABC to 16.31 million lb (7.40 million kg). In April 2022, the Council began work on a new framework action to adjust the red snapper catch limits consistent with these recommendations.

The Council approved both the Data Calibration Framework Action and the Catch Limits Framework Action at its April 2021 meeting. However, NMFS expressed concern about the Council's proposal to delay implementation of the Calibration Framework until 2023, and requested that the Council reconsider that implementation timing. The Council discussed the request at its August 2021 meeting but did not make any changes to the implementation date of the preferred alternative.

Management Measures Contained in This Proposed Rule

This proposed rule would modify the state-specific red snapper private angling component ACLs using the calibration ratios adopted by the Council, and increase the red snapper ACLs and ACTs consistent with the red snapper interim analyses and the subsequent SSC recommendations. The calibrations are necessary to convert the state private angling component ACLs into the same ''currency'' in which each state monitors landings by the private angling component. This would reduce the likelihood of exceeding the red snapper private angling component ACL, the total recreational ACL, and the OFL.

ACLs and ACTs

If implemented, this proposed rule would increase the Gulf red snapper catch limits. The stock ACL would increase from 15,100,000 lb (6,800,000 kg) to 15,400,000 lb (7,000,000 million kg). The commercial ACL (commercial quota) would increase from 7,701,000 lb (3,493,000 kg) to 7,854,000 lb (3,562,514 kg), and the recreational ACL (recreational quota) would increase from 7,399,000 lb (3,356,000 kg) to 7,546,000 lb (3,422,808 kg). The for-hire component recreational ACL would increase from 3,130,000 lb (1,420,000 kg) to 3,191,958 lb (1,447,848 kg). The private angling component recreational ACL would increase from 4,269,000 lb (1,936,000 kg) to 4,354,042 lb (1,974,960 kg). In addition, the private angling recreational ACT would increase from 3,415,000 lb (1,549,000 million kg kg) to 3,483,234 lb (1,579,968 kg).

For the Federal for-hire component, the Council chose to maintain the current buffer between the ACL and ACT at 9 percent to minimize the risk of ACL overages. Therefore, as a result, the for-hire component ACT would increase from 2,848,000 lb (1,292,000 kg) to 2,904,682 lb (1,317,542 kg).

Because of the increased recreational private angling component ACL in this proposed rule, each Gulf state would be initially allocated an increase in their specific state private angling component ACL. Alabama's ACL would increase from 1,122,662 lb (509,231 kg) to 1,145,026 lb (519,375 kg); Florida's ACL would increase from 1,913,451 lb (867,927 kg) to 1,951,569 lb (885,217 kg); Louisiana's ACL would increase from 816,233 lb (370,237 kg) to 832,493 lb (377,612 kg); Mississippi's ACL would increase from 151,550 lb (68,742 kg) to 154,568 lb (70,110 kg); and Texas's ACL would increase from 265,105 lb (120,250 kg) to 270,386 lb (122,645 kg). The above proposed changes to state catch limits are based on the Catch Limits Framework. These are not the final catch limits that would be implemented through this proposed rule and they are not included in the codified text in this rule because the calibration ratios need to be applied as described in the following paragraph.

Each Gulf state's private angling component ACL in the prior paragraph would be modified by applying the calibration ratios adopted by the Council. The final private angling component ACLs followed by the Federal equivalent are as follows: the Alabama private angling component ACL would be 558,200 lb (253,195 kg) or Federal equivalent of 1,145,026 lb (519,375 kg); The Florida private angling component ACL would be 2,069,053 lb (938,507 kg) or Federal equivalent of 1,951,569 lb (885,217 kg); The Louisiana private angling component ACL would be 882,443 lb (400,269 kg) or Federal equivalent of 832,493 lb (337,612 kg); the Mississippi private angling component ACL would be 59,354 lb (26,923 kg) or Federal equivalent of 154,568 lb (70,111 kg); and the Texas private angling component ACL (Equal to Federal) would be 270,386 lb (122,645 kg). Each state will use its reporting system to monitoring landings and appropriately constrain harvest to its ACL. NMFS will convert the state landings estimates to the Federal ''currency'' to determine whether landings have been constrained to the private angling ACL, total recreational ACL (quota) and OFL. This is necessary because the private angling ACL, total recreational ACL (quota) and OFL will remain in the Federal ''currency.''

Minority Report

A minority report signed by three Council members raised objections to the Council's decision to approve the Calibration Framework with an implementation date of January 1, 2023 included in the preferred alternative. These Council members were concerned that delaying implementation until 2023 would allow 2 additional fishing years (2021 and 2022) where the private angling component of the recreational sector would be allowed to catch more than its allocation of red snapper. NMFS invites specific comment on the proposed implementation date of January 1, 2023, and has otherwise determined that the proposed rule is consistent with the Magnuson-Stevens Act. Any final rule will respond to comments on the proposed rule received by NMFS during the comment period, as well as the issues raised in the Council's minority report. The minority report is available at the website: *https://gulfcouncil.org/wp-content/uploads/Council-Minority-Report-FINAL-Signatures.pdf.*

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the framework actions, the FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The factual basis for this determination follows.

A description of this proposed rule, why it is being considered, and the objectives of this proposed rule are contained in the preamble. The Magnuson-Stevens Act provides the statutory basis for this proposed rule. No duplicative, overlapping, or conflicting Federal rules have been identified. In addition, no new reporting, record-keeping, or other compliance requirements are introduced by this proposed rule.

This proposed rule would apply to all federally-permitted commercial vessels, federally-permitted charter vessels and headboats (for-hire vessels), and recreational anglers that fish for or harvest red snapper in Federal waters of the Gulf. It would also apply to red snapper IFQ shareholders. It would not directly apply to federally-permitted dealers. Any change in the supply of red snapper available for purchase by dealers as a result of this proposed rule, and associated economic effects, would be an indirect effect of the proposed rule and would therefore fall outside the scope of the RFA. Similarly, although it would apply to for-hire vessels, it would not be expected to have any direct effects on these entities. For-hire vessels sell fishing services to recreational anglers. The proposed changes to the red snapper management measures would not directly alter the services sold by these vessels. Any change in demand for these fishing services, and associated economic effects, as a result of this proposed rule would be a consequence of a change in anglers' behavior, secondary to any direct effect on anglers and, therefore, an indirect effect of the proposed rule. Because the effects on for-hire vessels would be indirect, they fall outside the scope of the RFA. Furthermore, for-hire captains and crew are not allowed to retain red snapper under the recreational bag limits, so only recreational anglers would be directly affected by the proposed changes to the red snapper recreational ACLs and ACTs. The RFA does not consider recreational anglers to be small entities, so they are outside the scope of this analysis (5 U.S.C. 603). Small entities include small businesses, small organizations, and small governmental jurisdictions (5 U.S.C. 601(6) and 601(3)–(5)). Recreational anglers are not businesses, organizations, or governmental jurisdictions. In summary, commercial vessels and IFQ shareholders are the only small entities that would be directly affected by the proposed rule, and therefore only the impacts on these small entities will be discussed.

As of April 26, 2021, after the Council approved both framework actions, there were 827 limited access valid or renewable commercial Gulf reef fish permits. In order to harvest red snapper, a vessel permit must also be linked to an IFQ account and possess sufficient allocation for this species. IFQ accounts can be opened and valid permits can be linked to IFQ accounts at any time during the year. Eligible vessels can receive red snapper allocation from other IFQ participants. On average, from 2015 through 2019, there were 637 IFQ accounts that held red snapper allocation and 364 that held red snapper shares. During the same time period, there were 434 federally-permitted commercial vessels, on average each year, with reported landings of red snapper in the Gulf. Their average annual vessel-level gross revenue from all species for 2015 through 2019 was approximately $147,000 (2019 dollars) and red snapper accounted for approximately half of this revenue. The maximum annual revenue from all species reported by a single one of the commercial vessels that landed Gulf red snapper from 2015 through 2019 was approximately $2.7 million (2019 dollars).

For RFA purposes only, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (NAICS code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $11 million for all its affiliated operations worldwide. All of the commercial fishing businesses directly regulated by this proposed rule are believed to be small entities based on the NMFS size standard.

No other small entities that would be directly affected by this proposed rule have been identified.

This proposed rule would modify the red snapper ACLs and recreational ACTs based on the OFL and ABC recommendations of the Council's SSC and ratio calibrations adopted by the Council for the state-specific red snapper private angling components. Under this proposed rule, the commercial ACL (quota) would increase by 153,000 lb (69,399 kg), which, if harvested in full, would correspond to an estimated increase in annual ex-vessel revenue of $719,000 (2019 dollars). Divided by the average number of commercial vessels with reported landings of red snapper from 2015 through 2019, this would be an increase of approximately $1,657 (2019 dollars) per vessel. In addition to the expected increase in ex-vessel revenue, the proposed increase in the commercial red snapper quota would be expected to result in an annual increase in allocation value of approximately $0.5 million (2019 dollars). Finally, total red snapper IFQ share value would be expected to increase by approximately $5.6 million (2019 dollars). These estimates rely on average ex-vessel, IFQ allocation, and IFQ share price estimates from 2019. Actual future prices could increase or decrease relative to 2019 as a result of market forces. NMFS expects that any negative price effects induced by this proposed rule, should they occur, would be outweighed by the benefits of the increased commercial quota.

In summary, the information provided above supports a determination that this proposed rule would not have a significant economic impact on a substantial number of small entities. As a result, an initial regulatory flexibility analysis is not required and none has been prepared.

This proposed rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

List of Subjects in 50 CFR Part 622

Annual catch limits, Fisheries, Fishing, Gulf, Red snapper, Reef fish, Quota.

Dated: June 22, 2022.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 622 is proposed to be amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF OF MEXICO, AND SOUTH ATLANTIC

■ 1. The authority citation for part 622 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 622.23, revise paragraph (a)(1)(ii) to read as follows:

§ 622.23 State management of the red snapper recreational sector private angling component in the Gulf EEZ.

(a) * * *

(1) * * *

(ii) *State private angling component ACLs.* All ACLs specified below are in round weight and are consistent with monitoring under the respective state's reporting system. Equivalent ACLs, consistent with monitoring under the Federal reporting system, are provided, as applicable. If a state's delegation is

suspended, as described in paragraph (a)(1) of this section, the Federal equivalent ACL, or for the Texas regional management area the ACL in paragraph (a)(1)(ii)(E), applies in the EEZ off that state.

(A) *Alabama regional management area*—558,200 lb (253,195 kg); Federal equivalent—1,145,026 lb (519,375 kg).

(B) *Florida regional management area*—2,069,053 lb (938,507 kg); Federal equivalent—1,951,569 lb (885,217 kg).

(C) *Louisiana regional management area*—882,443 lb (400,269 kg); Federal equivalent—832,493 lb (337,612 kg).

(D) *Mississippi regional management area*—59,354 lb (26,923 kg); Federal equivalent—154,568 lb (70,111 kg).

(E) *Texas regional management area*—270,386 lb (122,645 kg).

* * * * *

■ 3. In § 622.39, revise paragraphs (a)(1)(i) and (a)(2)(i) to read as follows:

§ 622.39 Quotas.

* * * * *

(a) * * *

(1) * * *

(i) Commercial quota for red snapper—7,854,000 lb (3,562,514 kg), round weight.

* * * * *

(2) * * *

(i) *Recreational quota for red snapper*—(A) *Total recreational.* The total recreational quota is 7,546,000 lb (3,422,808 kg), round weight.

(B) *Federal charter vessel/headboat component quota.* The Federal charter vessel/headboat component quota applies to vessels that have been issued a valid Federal charter vessel/headboat permit for Gulf reef fish any time during the fishing year. A person aboard a vessel that has been issued a charter vessel/headboat permit for Gulf reef fish any time during the fishing year may not harvest or possess red snapper in or from the Gulf EEZ when the Federal charter vessel/headboat component is closed. The Federal charter vessel/headboat component quota is 3,191,958 lb (1,447,848 kg), round weight.

(C) *Private angling component quota.* The private angling component quota applies to vessels that fish under the bag limit and have not been issued a Federal charter vessel/headboat permit for Gulf reef fish any time during the fishing year. The private angling component quota is 4,354,042 lb (1,974,960 kg), round weight.

* * * * *

■ 4. In § 622.41, revise the last sentence in paragraphs (q)(2)(iii)(B) and (q)(2)(iii)(C) to read as follows:

§ 622.41 Annual catch limits (ACLs), annual catch targets (ACTs), and accountability measures (AMs).

* * * * *

(q) * * *

(2) * * *

(iii) * * *

(B) * * * The component ACT is 2,904,682 lb (1,317,542 kg), round weight.

(C) * * * The component ACT is 3,483,234 lb (1,579,968 kg), round weight.

[FR Doc. 2022–13695 Filed 6–27–22; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 87, No. 123
Tuesday, June 28, 2022

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

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

Comments regarding this information collection received by July 28, 2022 will be considered. 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 information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

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

Food and Nutrition Service

Title: Uniform Grant Application for Non-Entitlement Discretionary Grants.

OMB Control Number: 0584–0512.

Summary of Collection: The Food and Nutrition Service (FNS) has a number of non-entitlement discretionary grant programs to collect the information from grant applicants needed to evaluate and rank applicants and protect the integrity of the grantee selection process. All FNS discretionary grant programs will be eligible, but not required to use the uniform grant application package. The authorities for these grants vary. The term ''grant'' in this submission refers only to non-entitlement discretionary competitive and non-competitive grants or cooperative agreements. Discretionary grant announcements include a number of information collections, including the submission of associated State Plan information and the use of program-specific forms, including but not limited to, Form FNS–887 Farm to School Coversheet, the Farm to School Baseline Report, and the Farm to School Final Report; a ''project description'' (program narrative), budget information SF425, disclosure of lobbying activities certification SF LLL, and disclosure of Corporate Felony Convictions and Corporate Federal Tax Delinquencies. The requirements for the program narrative statement are based on the requirements for program narrative statements described in section 1.c (5) of OMB Circular A–102 and OMB A–110 (as implemented at USDA 7 CFR part 3015, 3016 and 3019); and will apply to all types of grantees; State and local governments, non-profit organizations, institutions of higher education, hospitals, and for-profit organizations.

If FNS decides to use the uniform grant application package, FNS will note in the grant solicitation that applicants must use the uniform grant application package and that the information collection has already been approved by OMB. If FNS decides not to use the uniform grant application package or determines that it needs grant applicants to provide additional information not contained in the uniform package, then FNS will publish at least a 30 day notice soliciting comments on its proposal to collect different or additional information before making the grant solicitation, if not already discussed in previously published notices.

Through this **Federal Register** Notice, FNS is notifying the public of additional grants and forms added to this Information Collection Request (ICR) since the associated 60-day FR Notice was published on (April 19, 2022) at (87 FR 23160). The additional grants and total burden hours for each one added to this ICR since the 60-day FR Notice include the following: (1) Center for Food Safety Research in Child Nutrition grant, 260, (2) Special Supplemental Nutrition Program for Women, Infants and Children—Breastfeeding, 820, (3) Special Supplemental Nutrition Program for Women, Infants and Children—Special Projects, 726, (4) SNAP Income Improvements and Verification Grant, 882, (5) Special Supplemental Nutrition Program for Women, Infants and Children—Technology grants, 6678, (6) Institute of Child Nutrition Annual Food Safety Cooperative Agreement (SNAS Office of Food Safety), 70, (7) Special Supplemental Nutrition Program for Women, Infants and Children—WIC online shopping Technical Assistance and subgrantees, 1328, (8) Special Supplemental Nutrition Program for Women, Infants and Children—Community innovation and outreach grant and subgrantees, 3680, (9) SNAP E&T National Partnership Grants, 882, (10) Healthy Meals Incentives 19,951.

Need and Use of the Information: The primary users of the information collected from the applicant are FNS and other Federal staff who will serve on a panel to systematically review, evaluate, and approve the competitive and non-competitive grant/cooperative agreement applications and recommend the applicants most likely to meet program objectives and most responsive to the solicitation. The selection criteria will be contained in the Request for Application package. Without this information, FNS will not have adequate data to select appropriate grantees or evaluate which grants should be continued or monitor financial reporting requirements.

Description of Respondents: State, Local, or Tribal Government (6,426); Business or other for-profit; Not for profit institutions (541).

Number of Respondents: 6,967.

Frequency of Responses: Reporting: annually, (one-time); quarterly, on occasion.

Total Burden Hours: 1,500,000.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2022–13722 Filed 6–27–22; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Proposed New Fee Sites

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of proposed new fee sites.

SUMMARY: The Shasta-Trinity National Forest is proposing to charge new fees at multiple recreation sites listed in **SUPPLEMENTARY INFORMATION** of this notice. Funds from fees would be used for operation, maintenance, and improvements of these recreation sites. An analysis of nearby developed recreation sites with similar amenities shows the proposed fees are reasonable and typical of similar sites in the area.

DATES: If approved, the new fee would be implemented no earlier than six months following the publication of this notice in the **Federal Register**.

ADDRESSES: Shasta-Trinity National Forest, 204 West Alma Street, Mount Shasta, CA 96067.

FOR FURTHER INFORMATION CONTACT: Jennifer Womack, Recreation Special Uses Administrator, 530–925–9306 or *jennifer.womack@usda.gov.*

SUPPLEMENTARY INFORMATION: The Federal Recreation Lands Enhancement Act (Title VII, Pub. L. 108–447) directed the Secretary of Agriculture to publish a six-month advance notice in the **Federal Register** whenever new recreation fee areas are established. The fees are only proposed at this time and will be determined upon further analysis and public comment.

Reasonable fees, paid by users of these sites, will help ensure that the Forest can continue maintaining and improving recreation sites like this for future generations.

As part of this proposal, the Ripstein, Horse Flat, Scott Mountain, Goldfield, Denny, Hobo Gulch, Trout Creek Meadow, Algoma, Deerlick Springs, Big Slide, Scott Flat, Slide Creek, and Jackass Springs campgrounds are proposing $15 per night. The Panther Meadows and Castle Lake campgrounds are proposing $20 per night. In addition, this proposal would implement new fees at three recreation rentals: Knob Peak Lookout at $90 per night along with the Forest Glen House and Harrison Gulch Ranger Station, both at $150 per night.

A $5 day-use fee per vehicle or $40 annual pass is proposed at Bunny Flat Trailhead, Everitt Memorial Vista, Red Fir Flat, Castle Lake Picnic, Upper Falls Picnic Area, Middle Falls Picnic Area, Lower Falls Picnic Area, Lakin Dam Picnic Area, Camp 4 Day Use Area, Cattle Camp Picnic Area, Pollard Gulch, Snowman's Hill Snowpark Day Use, Parks Creek Trailhead, Cabin Creek Trailhead, Big Flat River Access, Pigeon Point Boating Site, Canyon Creek Trailhead, Stuart Fork Trailhead, Swift Creek Trailhead, and Long Canyon Trailhead. The full suite of Interagency passes would be honored.

New fees would provide increased visitor opportunities, as well as increased staffing to address operations and maintenance needs and enhance customer service. Once public involvement is complete, these new fees will be reviewed by a Recreation Resource Advisory Committee prior to a final decision and implementation.

Advanced reservations for campgrounds and cabins will be available through *www.recreation.gov* or by calling 1–877–444–6777. The reservation service charges an $8.00 fee for reservations.

Dated: June 22, 2022.

Sandra Watts,

Acting Associate Deputy Chief, National Forest System.

[FR Doc. 2022–13675 Filed 6–27–22; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Superior National Forest; Minnesota; Rainy River Withdrawal Environmental Assessment

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of opportunity to comment on environmental assessment for the Rainy River Withdrawal Application.

SUMMARY: The Forest Service, U.S. Department of Agriculture, has prepared an environmental assessment to support its application for a 20-year withdrawal of the Rainy River watershed from disposition of Federally owned minerals under United States mineral and geothermal leasing laws. The intent of the requested withdrawal is to protect and preserve natural and cultural resources in the Rainy River watershed, including the Boundary Waters Canoe Area Wilderness (BWCAW), Mining Protection Area (MPA), and the 1854 Ceded Territory, from the known and potential adverse environmental impacts arising from exploration and development of Federally owned minerals. This notice is to inform the public that the Superior National Forest is initiating a 30-day period in which individuals or entities may submit comments relevant to the environmental assessment.

DATES: Comments concerning the environmental assessment must be received by July 28, 2022.

ADDRESSES: The environmental assessment and supporting documents are available on the project web page at *http://go.usa.gov/xtaCw.* Electronic comments are preferred through the project website at *https://go.usa.gov/xuH43.* Comments may also be sent electronically to *comments-eastern-superior@usda.gov.* Written comments may be sent to Forest Headquarters, 8901 Grand Avenue Place, Duluth, MN 55808.

FOR FURTHER INFORMATION CONTACT: Matt Judd, Minerals Project Manager, at *matthew.judd@usda.gov* or 218–626–4300. Individuals who use telecommunication devices for the deaf and hard of hearing (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION:

Purpose and Need for Action

The purpose of the requested withdrawal is to protect and preserve natural and cultural resources in the Rainy River watershed, including the BWCAW, MPA, and the 1854 Ceded Territory, from the known and potential adverse environmental impacts arising from exploration and development of Federally owned minerals. The withdrawal is needed because the Forest Service and the Bureau of Land Management (BLM) have seen and can reasonably anticipate increasing interest within the private sector for developing the copper-nickel ore minerals in the Duluth Complex that may adversely impact the Rainy River watershed.

Proposed Action

The Secretary of the Interior would issue a public land order, and approximately 225,504 acres of National Forest System lands in the Rainy River watershed would be withdrawn from disposition under the United States mineral and geothermal leasing laws for

a 20-year term, subject to valid existing rights. The withdrawal would restrict the BLM from processing or issuing new hardrock prospecting permits and mineral leases on National Forest System lands in the withdrawal boundary. However, the withdrawal would not prohibit ongoing or future exploration or mining extraction operations on valid existing rights, as determined by the BLM.

The withdrawal would not prohibit activities on non-federal (surface and mineral) ownerships. State, county, and private mineral interests could continue to exercise their ownership rights. However, if fee simple title of these lands and minerals were acquired by the United States during the withdrawal period, through means such as purchase or exchange to be managed by the Forest Service, such acquisitions would be subject to the withdrawal. Partial federal mineral interests, where the Federal government owns less than 100 percent of the mineral estate, would also not be affected by the withdrawal. No other management changes would be made affecting access to private inholdings, federal mineral material operations (sand, gravel, and dimension stone), or management of other forest resources such as timber, wildlife, and recreation.

Lead and Cooperating Agencies

The Forest Service is the lead agency for preparing the environmental assessment. The BLM is a cooperating agency for the NEPA analysis (40 CFR 1508.1(e)). The BLM will independently evaluate and review the analysis and any other documents needed for the Secretary of the Interior to make a decision on the requested withdrawal.

Responsible Official

The Secretary of the Interior is the decision-maker for the requested withdrawal.

How To Comment

Comments may be submitted in electronic (preferred) or hard-copy form to the website or addresses provided in the **ADDRESSES** section of this notice. It is important that reviewers provide their comments at such times and in such manner that they are useful to the agency's preparation of the environmental assessment. Therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and contentions.

The proposed withdrawal is not subject to Forest Service objection procedures at 36 CFR 218 because the decision to be made is by the Secretary of the Interior.

Dated: June 8, 2022.

Debbie Hollen,

Acting Associate Deputy Chief, National Forest System.

[FR Doc. 2022–13776 Filed 6–27–22; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Proposed New Fee Sites

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of proposed new fee sites.

SUMMARY: The Sierra National Forest is proposing to charge new fees at multiple recreation sites listed in **SUPPLEMENTARY INFORMATION** of this notice. Funds from fees would be used for operation, maintenance, and improvements of these recreation sites. Many sites have recently been reconstructed or amenities are being added to improve services and experiences. An analysis of nearby developed recreation sites with similar amenities shows the proposed fees are reasonable and typical of similar sites in the area.

DATES: If approved, the new fee would be implemented no earlier than six months following the publication of this notice in the **Federal Register**.

ADDRESSES: Sierra National Forest, 1600 Tollhouse Road, Clovis, CA 93611.

FOR FURTHER INFORMATION CONTACT: Jody Nickerson-Powell, Forest Recreation Officer, 559–797–7410 or *jody.nickerson@usda.gov.*

SUPPLEMENTARY INFORMATION: The Federal Recreation Lands Enhancement Act (Title VII, Pub. L. 108–447) directed the Secretary of Agriculture to publish a six-month advance notice in the **Federal Register** whenever new recreation fee areas are established. The fees are only proposed at this time and will be determined upon further analysis and public comment.

Reasonable fees, paid by users of these sites, will help ensure that the Forest can continue maintaining and improving recreation sites like this for future generations.

As part of this proposal, the Jerseydale campground fee is proposed at $20 per night. The Kirch Flat campground fee is proposed at $20 per night plus a $5 extra vehicle fee. Kirch Flat group campground fee is proposed at $100 per night with a $5 extra vehicle fee over 14 vehicles.

New fees would provide increased visitor opportunities, as well as increased staffing to address operations and maintenance needs and enhance customer service. Once public involvement is complete, these new fees will be reviewed by a Recreation Resource Advisory Committee prior to a final decision and implementation.

Advanced reservations for campgrounds and cabins will be available through *www.recreation.gov* or by calling 1–877–444–6777. The reservation service charges an $8.00 fee for reservations.

Dated: June 22, 2022.

Sandra Watts,

Acting Associate Deputy Chief, National Forest System.

[FR Doc. 2022–13676 Filed 6–27–22; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–101–2022]

Foreign-Trade Zone 68—El Paso, Texas; Application for Expansion of Subzone 68A; Expeditors International of Washington, Inc.; El Paso, Texas

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the City of El Paso, grantee of FTZ 68, requesting expanded subzone status for the facilities of Expeditors International of Washington, Inc., located in El Paso, Texas. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on June 22, 2022.

Subzone 68A was approved on March 5, 2013 (S–3–2013, 78 FR 15683, March 12, 2013). The subzone currently consists of the following sites: *Site 1* (2.94 acres)—1450 Pullman Drive, El Paso; and *Site 2* (4.02 acres)—1313 Don Haskins Drive, El Paso.

The applicant is requesting authority to expand the subzone to include an additional site in El Paso: Proposed Site 3 (24.318 acres)—1401 Pullman Drive, Suites A and B, El Paso. No authorization for production activity has been requested at this time. The proposed expanded subzone would be subject to the existing activation limit of FTZ 68.

In accordance with the FTZ Board's regulations, Camille Evans of the FTZ Staff is designated examiner to review the application and make recommendations to the Executive Secretary.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive

Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is August 8, 2022. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to August 22, 2022.

A copy of the application will be available for public inspection in the ''Online FTZ Information Section'' section of the FTZ Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Camille Evans at *Camille.Evans@trade.gov.*

Dated: June 23, 2022.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2022–13775 Filed 6–27–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–837]

Polyethylene Terephthalate Film, Sheet, and Strip From Taiwan: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2020–2021

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) is conducting an administrative review of the antidumping duty order on polyethylene terephthalate film, sheet, and strip (PET Film) from Taiwan. The period of review (POR) is July 1, 2020, through June 30, 2021. This review covers the following producers and exporters from Taiwan: Nan Ya Plastics Corporation (Nan Ya); and Shinkong Materials Technology Corporation (SMTC)/Shinkong Synthetic Fibers Corporation (SSFC). Commerce preliminarily determines that sales of subject merchandise have not been made below normal value (NV) by Nan Ya during the POR. In addition, we preliminarily find that SMTC/SSFC had no shipments during the POR. Interested parties are invited to comment on these preliminary results.

DATES: Applicable June 28, 2022.

FOR FURTHER INFORMATION CONTACT: Charles DeFilippo or Jacqueline Arrowsmith, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3797 or (202) 482–5255, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 1, 2021, Commerce published in the **Federal Register** a notice of opportunity [1] to request an administrative review of the AD order on PET film from Taiwan.[2] On September 7, 2021, in accordance with 19 CFR 351.221(c)(1)(i), Commerce published a notice of initiation of an administrative review of the *Order.*[3]

On March 3, 2022, in accordance with section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.213(h)(2), Commerce extended the due date for the preliminary results by 80 days until June 21, 2022.[4] For a complete desciription of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[5]

A list of the topics included in the Preliminary Decision Memorandum is included as the appendix 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 *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Order

The merchandise subject to the *Order* is PET film. The PET film subject to the *Order* is currently classifiable under subheading 3920.62.00.90 of the Harmonized Tariff Schedule of the United States. Although the HTSUS number is provided for convenience and for customs purposes, the written product description, available in the PDM, remains dispositive.

Preliminary Determination of No Shipments

Based on U.S. Customs and Border Protection's (CBP) response to Commerce's no shipment inquiry as well the certifications and supporting documentation provided by SMTC/SSFC [6] in its no shipment certification, we preliminarily determine that SMTC/SSFC had no shipments of the subject merchandise during the POR. Consistent with Commerce's practice, we will not rescind the review with respect to SMTC/SSFC, but rather will complete the review and issue appropriate liquidation instructions to CBP based on the final results.[7] For additional information regarding this determination, *see* the Preliminary Decision Memorandum.[8]

Methodology

Commerce is conducting this review in accordance with section 751(a)(2) of the Tariff Act of 1930, as amended (the Act). Export price is calculated in accordance with section 772 of the Act. NV is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying these preliminary results, *see* the Preliminary Decision Meorandum.

Preliminary Results of Review

As a result of this review, Commerce preliminarily determines that the following weighted-average dumping margin exists for the period July 1, 2020, through June 30, 2021:

[1] *See Antidumping or Countervailing Duty Order, Finding or Suspended Investigation; Opportunity to Request Administrative Review,* 86 FR 35065 (July 1, 2021).

[2] *See Notice of Amended Final Antidumping Duty Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Polyethylene Terephthalate Film, Sheet, and Strip (PET Film) from Taiwan,* 67 FR 44174 (July 1, 2002) (*Order*).

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 50034 (September 7, 2021).

[4] *See* Memorandum, ''Polyethylene terephthalate (PET) film, sheet, and strip from Taiwan: Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,'' dated March 3, 2022.

[5] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments: Polyethylene Terephthalate Film, Sheet, and Strip from Taiwan; 2020–2021'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[6] In the 2011–2012 administrative review, we treated SMTC and SSFC as a single entity for purposes of this order. *See Polyethylene Terephthalate Film, Sheet, and Strip from Taiwan; Preliminary Results of Antidumping Duty Administrative Review; 2011–2012,* 78 FR 48651 (August 9, 2013), and accompanying Preliminary Decision Memorandum, unchanged in *Polyethylene Terephthalate Film, Sheet, and Strip from Taiwan: Final Results of Antidumping Duty Administrative Review; 2011–2012,* 79 FR 11407 (February 28, 2014). We have treated SMTC and SSFC as a single entity in all subsequent reviews. There is no information on the record of this administrative review that would lead Commerce to reconsider that determination. Accordingly, we continue to treat SMTC and SSFC as a single entity for purposes of this administrative review.

[7] *See Polyethylene Terephthalate Film, Sheet, and Strip from Taiwan: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2018–2019,* 85 FR 74673 (November 23, 2020), unchanged in *Polyethylene Terephthalate Film, Sheet, and Strip (PET Film) from Taiwan: Final Results of Antidumping Duty Administrative Review; 2018–2019,* 86 FR 14311 (March 15, 2021).

[8] *See* Preliminary Decision Memorandum.

Producer/exporter	Weighted-average dumping margin (percent)
Nan Ya Plastics Corporation	0.00

Disclosure and Public Comment

Commerce intends to disclose its calculations and analysis performed to interested parties to these preliminary results within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than seven days after the date for filing case briefs.[9] Parties who submit case or rebuttal briefs in this proceeding 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.[10]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the publication date 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. Issues raised in the hearing will be limited to those raised in the respective case briefs. If a hearing is requested, Commerce will notify interested parties of the hearing date and time. Parties should confirm by telephone the date and time of the hearing two days before the scheduled hearing date.

Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, unless extended, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon completion of this administrative review, Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries. If a respondent's weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.5 percent) in the final results of this review, we will calculate importer-specific *ad valorem* assessment rates on the basis of the ratio of the total amount of dumping calculated for an importer's examined sales and the total entered value of such sales in accordance with 19 CFR 351.212(b)(1). Where either the respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c), or an importer-specific rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this administrative review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of PET film from Taiwan entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review, as provided for by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for the company under review will be the rate established in the final results of this review (except, if the rate is zero or *de minimis,* no cash deposit will be required); (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the less-than-fair value investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other producers or exporters is 2.40 percent.[11] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary 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.

Notification to Interested Parties

We are issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(h)(1).

Dated: June 21, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2022–13771 Filed 6–27–22; 8:45 am]

BILLING CODE 3510–DS–P

[9] *See* 19 CFR 351.309(d).

[10] *See* 19 CFR 351.303 (for general filing requirements).

[11] *See Order.*

DEPARTMENT OF COMMERCE

International Trade Administration

[C–821–837]

Sodium Nitrite From the Russian Federation: Final Affirmative Countervailing Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers and exporters of sodium nitrite from the Russian Federation (Russia) during the period of investigation January 1, 2021, through December 31, 2021.

DATES: Applicable June 28, 2022.

FOR FURTHER INFORMATION CONTACT: Melissa Porpotage, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1413.

SUPPLEMENTARY INFORMATION:

Background

The petitioner in this investigation is Chemtrade Chemicals US LLC. In addition to the Government of Russia

(GOR), the mandatory respondent in this investigation is UralChem, JSC (UralChem).

On April 15, 2022, Commerce published in the **Federal Register** the *Preliminary Determination* of this investigation.[1] We received no comments or case briefs addressing any of the findings in the *Preliminary Determination*; therefore, there is no unpublished Issues and Decision Memorandum accompanying this notice.

Period of Investigation

The period of investigation is January 1, 2021, through December 31, 2021.

Scope of the Investigation

The scope of this investigation covers sodium nitrite in any form, at any purity level from Russia. For a complete description of the scope of this investigation, *see* the appendix to this notice.

Analysis of Subsidy Programs—Adverse Facts Available (AFA)

For purposes of this final determination, we relied solely on facts available pursuant to section 776 of the Tariff Act of 1930, as amended, (the Act) because neither the GOR nor the selected mandatory respondent, UralChem, participated in this investigation. Further, because UralChem and the GOR did not cooperate to the best of their abilities in responding to our requests for information in this investigation, we drew adverse inferences in selecting from among the facts otherwise available, in accordance with sections 776(a)–(b) of the Act. Consistent with the *Preliminary Determination,*[2] we continue to apply AFA to determine the appropriate subsidy rates for this investigation. No interested party submitted comments on the subsidy rates selected in the *Preliminary Determination*. Thus, we made no changes to the subsidy rates for the final determination. A detailed discussion of our application of AFA is provided in the *Preliminary Determination*.[3]

All-Others Rate

As discussed in the *Preliminary Determination,* Commerce based the selection of the all-others rate on the countervailable subsidy rate established for the mandatory respondent, in accordance with section 705(c)(5)(A)(ii) of the Act.[4] We made no changes to the selection of the all-others rate for this final determination.

Final Determination

Commerce determines that the following estimated countervailable subsidy rates exist:

Company	Subsidy rate (percent *ad valorem*)
UralChem, JSC	386.24
All Others	386.24

Disclosure

Normally, Commerce discloses to interested parties the calculations performed in connection with a final determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of final determination in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because there are no changes to the calculations from the *Preliminary Determination,* no additional disclosure is necessary.

Continuation of Suspension of Liquidation

In accordance with section 705(c)(4)(A) of the Act, Commerce intends to instruct U.S. Customs and Border Protection (CBP) to continue to suspend the liquidation of all appropriate entries of subject merchandise, as described in the appendix of this notice, entered, or withdrawn from warehouse, for consumption on or after April 15, 2022, which is the date of publication of the affirmative *Preliminary Determination* in the **Federal Register**, at the cash deposit rates indicated above. These suspension of liquidation instructions will remain in effect until further notice.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we intend to issue a countervailing duty order and continue to require a cash deposit of estimated countervailing duties for such entries of subject merchandise in the amounts indicated above, in accordance with section 706(a) of the Act. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated, and all estimated duties deposited as a result of the suspension of liquidation will be refunded or canceled.

ITC Notification

In accordance with section 705(d) of the Act, we intend to notify the ITC of our final affirmative determination that countervailable subsidies are being provided to producers and exporters of sodium nitrite from Russia. Because the final determination in this proceeding is affirmative, in accordance with section 705(b) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of sodium nitrite from Russia no later than 45 days after our final determination.

If the ITC determines that material injury or threat of material injury does not exist, this proceeding will be terminated and all cash deposits will be refunded or canceled, as Commerce determines to be appropriate. If the ITC determines that such injury does exist, Commerce intends to issue a countervailing duty order directing CBP to assess, upon further instruction by Commerce, countervailing duties on all imports of the subject merchandise that are entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the ''Continuation of Suspension of Liquidation'' section.

Administrative Protective Order (APO)

In the event that the ITC issues a final negative injury determination, this notice will serve as the only reminder to parties subject to an APO of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

This determination is issued and published pursuant to sections 705(d) and 777(i) of the Act, and 19 CFR 351.210(c).

Dated: June 22, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

Scope of the Investigation

The product covered by this investigation is sodium nitrite in any form, at any purity level. In addition, the sodium nitrite covered by this investigation may or may not contain an anti-caking agent. Examples of names

[1] *See Sodium Nitrite from the Russian Federation: Preliminary Affirmative Countervailing Duty Determination,* 87 FR 22504 (April 15, 2022) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See Preliminary Determination* PDM at 3–11.

[3] *Id.*

[4] *See Preliminary Determination,* 87 FR at 22504.

commonly used to reference sodium nitrite are nitrous acid, sodium salt, anti-rust, diazotizing salts, erinitrit, and filmerine. Sodium nitrite's chemical composition is NaNO2, and it is generally classified under subheading 2834.10.1000 of the Harmonized Tariff Schedule of the United States (HTSUS). The American Chemical Society Chemical Abstract Service (CAS) has assigned the name ''sodium nitrite'' to sodium nitrite. The CAS registry number is 7632–00–0. For purposes of the scope of this investigation, the narrative description is dispositive, not the tariff heading, CAS registry number or CAS name, which are provided for convenience and customs purposes.

[FR Doc. 2022–13772 Filed 6–27–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–821–836]

Sodium Nitrite From the Russian Federation: Preliminary Affirmative Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that sodium nitrite from the Russian Federation (Russia) is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is January 1, 2021, through December 31, 2021. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable June 28, 2022.

FOR FURTHER INFORMATION CONTACT: Paola Aleman Ordaz, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4031.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on February 8, 2022.[1] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[2] A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix II 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://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Investigation

The product covered by this investigation is sodium nitrite from Russia. For a full description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to Commerce's regulations,[3] in the *Initiation Notice,* we set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[4] No interested parties submitted comments on the scope of this investigation.

Methodology

Commerce is conducting this investigation in accordance with section 733 of the Act. Pursuant to section 776(a) and (b) of the Act, Commerce has preliminarily relied upon facts otherwise available, with adverse inferences, to determine the estimated weighted-average dumping margin for the sole mandatory respondent, *i.e.,* Uralchem, JSC (Uralchem). For a full description of the methodology underlying the preliminary determination, *see* the Preliminary Decision Memorandum.

All-Others Rate

Sections 733(d)(1)(ii) and 735(c)(5)(A) of the Act provide that in the preliminary determination Commerce shall determine an estimated all-others rate for all exporters and producers not individually examined. This rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding rates that are zero, *de minimis,* or determined entirely under section 776 of the Act.

In the situation where no estimated weighted-average dumping margins other than zero, *de minimis,* or those determined entirely under section 776 of the Act have been established for individually examined entities, in accordance with section 735(c)(5)(B) of the Act, Commerce may use ''any reasonable method to establish the estimated all-others rate for exporters and producers not individually investigated, including averaging the estimated weighted average dumping margins determined for the exporters and producers individually investigated.'' In this investigation, Commerce has preliminarily determined the estimated weighted-average dumping margin for Uralchem entirely under section 776 of the Act. Therefore, in the absence of a calculated estimated weighted-average dumping margin on the record of this investigation, we have preliminarily decided to assign the Petition rate of 207.17 percent to all other producers and exporters, pursuant to section 735(c)(5)(A) of the Act. For a full description of the methodology underlying Commerce's analysis, *see* the Preliminary Decision Memorandum.

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter/producer	Estimated weighted-average dumping margin (percent)	Cash deposit rate adjusted for subsidy offset (percent) [5]
Uralchem, JSC	207.17	25.73
All Others	207.17	25.73

[1] *See Sodium Nitrite from India and the Russian Federation: Initiation of Less-Than-Fair-Value Investigations,* 87 FR 7122 (February 2, 2022) (*Initiation Notice*).

[2] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination in the Less-Than-Fair-Value Investigation of Sodium Nitrite from the Russian Federation'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[3] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[4] *See Initiation Notice.*

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin or the estimated all-others rate, as follows: (1) The cash deposit rate for the respondents listed above will be equal to the company-specific estimated weighted-average dumping margins determined in this preliminary determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin. Commerce normally adjusts cash deposits for estimated antidumping duties by the amount of export subsidies countervailed in a companion countervailing duty (CVD) proceeding, when CVD provisional measures are in effect. Accordingly, where Commerce preliminarily made an affirmative determination for countervailable export subsidies, Commerce has offset the estimated weighted-average dumping margin by the appropriate CVD rate. Any such adjusted cash deposit rate may be found in the ''Preliminary Determination'' section above.

Should provisional measures in the companion CVD investigation expire prior to the expiration of provisional measures in this LTFV investigation, Commerce will direct CBP to begin collecting estimated antidumping duty cash deposits unadjusted for countervailed export subsidies at the time that the provisional CVD measures expire.

These suspension of liquidation instructions will remain in effect until further notice.

Disclosure

Normally, Commerce discloses to interested parties the calculations performed in connection with a preliminary determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of preliminary determination in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because Commerce preliminarily applied adverse facts available (AFA) to the individually examined company, Uralchem, in this investigation, in accordance with section 776 of the Act, and applied an AFA rate, which is based solely on the Petition, there are no calculations to disclose.

Verification

Because the sole mandatory respondent in this investigation did not provide any of the information requested by Commerce, and Commerce preliminarily determines that the respondent failed to cooperate by not acting to the best of its ability to respond to Commerce's request for information, pursuant to section 776(b) of the Act, we will not conduct verification.

Public Comment

Case briefs or other written comments on all issues may be submitted to the Assistant Secretary for Enforcement and Compliance no later than 21 days after the date of publication of the preliminarily determination.[6] Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than seven days after the deadline date for case briefs.[7] Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[8] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation 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.

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 for a hearing should contain: (1) the requesting party's name, address, and telephone number; (2) the number of individuals from the requesting party that will attend the hearing, including, whether any individuals are foreign nationals; and (3) a list of the issues the party intends to discuss at the hearing. Issues raised in the hearing will be limited to those raised in the case and rebuttal briefs. If a hearing is requested, Commerce will notify interested parties of the hearing date and time. Parties should confirm by telephone the date and time of the hearing two days before the scheduled hearing date.

International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the U.S. International Trade Commission (ITC) of its preliminary determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether these imports materially injure, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act, and 19 CFR 351.205(c).

Dated: June 22, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The product covered by this investigation is sodium nitrite in any form, at any purity level. In addition, the sodium nitrite covered by this investigation may or may not contain an anti-caking agent. Examples of names commonly used to reference sodium nitrite are nitrous acid, sodium salt, anti-rust, diazotizing salts, erinitrit, and filmerine. Sodium nitrite's chemical composition is $NaNO_2$, and it is generally classified under subheading 2834.10.1000 of the Harmonized Tariff Schedule of the United States (HTSUS). The American Chemical Society Chemical Abstract Service (CAS) has assigned the name ''sodium nitrite'' to sodium nitrite. The CAS registry number is

[5] In the preliminary determination of the companion CVD proceeding, Commerce applied the AFA rate of 45.36 percent to each of the following export subsidy programs: (1) Preferential Lending by Sberbank to Restructure $3.99 Billion in Uralchem Debt; (2) State Financing for Industrial Export Projects; (3) Russian Export Center (REC) Lending; and (4) State Specialized Russian Export-Import Bank (Eximbank) Financing. We subtracted 181.44 percent, the sum of the export subsidy rates, from the dumping margin of 207.17 percent.

[6] *See* 19 CFR 351.309(c)(1)(i); and 19 CFR 351.303 (for general filling requirements). Commerce has exercised its discretion under 19 CFR 351.309(c)(1)(i) to alter the time limit for submission of case briefs.

[7] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[8] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

7632–00–0. For purposes of the scope of this investigation, the narrative description is dispositive, not the tariff heading, CAS registry number or CAS name, which are provided for convenience and customs purposes.

Appendix II—List of Sections in the Preliminary Decision Memorandum

[FR Doc. 2022–13791 Filed 6–27–22; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–979]

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) has determined that the manufacturers/exporters of crystalline silicon photovoltaic cells, whether or not assembled into modules (solar cells), from the People's Republic of China (China) listed in the ''Final Results of Review'' section below, sold subject merchandise in the United States at less than normal value during the period of review (POR) December 1, 2019, through November 30, 2020.

DATES: Applicable June 28, 2022.

FOR FURTHER INFORMATION CONTACT: Jeff Pedersen, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2769.

SUPPLEMENTARY INFORMATION:

Background

On December 23, 2021, Commerce published the *Preliminary Results* of this review in the **Federal Register**.[1] After publication of the *Preliminary Results,* a number of interested parties filed case and rebuttal briefs and Commerce held a public hearing (*see* the Issues and Decision Memorandum for details).[2] On April 19, 2022, Commerce extended the deadline for the final results of this review until June 21, 2022.[3] The final weighted-average dumping margins determined in this review are in the ''Final Results of Review'' section of this notice.

Scope of the Order [4]

The merchandise covered by this *Order* is crystalline silicon photovoltaic cells, and modules, laminates, and panels, consisting of crystalline silicon photovoltaic cells, whether or not partially or fully assembled into other products, including, but not limited to, modules, laminates, panels and building integrated materials. Merchandise covered by this *Order* is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 8501.71.0000, 8501.72.1000, 8501.72.2000, 8501.72.3000, 8501.72.9000, 8501.80.1000, 8501.80.2000, 8501.80.3000, 8501.80.9000, 8507.20.8010, 8507.20.8031, 8507.20.8041, 8507.20.8061, 8507.20.8091, 8541.42.0010, and 8541.43.0010. Although these HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this order is dispositive. For a complete description of the scope of the *Order, see* the Issues and Decision Memorandum.

Analysis of Comments Received

We addressed all of the issues that were raised in interested parties' case and rebuttal briefs in the Issues and Decision Memorandum. A list of the sections in the Issues and Decision Memorandum, including a list of issues that parties raised, and to which we responded, is in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov*. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx*.

Final Determination of No Shipments

In the *Preliminary Results* we found that, during the POR, there were no shipments of subject merchandise into the United States by Canadian Solar,[5] JingAo Solar Co., Ltd., and Yingli.[6] No parties commented on these preliminary determinations. Accordingly, because we have not received any information to contradict our preliminary no-shipments determination, nor any comment in opposition to our preliminary finding, our determinations remain unchanged for the final results of review.[7] We will issue instructions to U.S. Customs Border and Protection (CBP) based on these final results.

Changes Since the Preliminary Results

As discussed in detail in the Issues and Decision Memorandum, since issuing the *Preliminary Results,* we corrected certain ministerial errors in

[1] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review, Partial Rescission of Antidumping Administrative Review, and Preliminary Determination of No Shipments; 2019–2020,* 86 FR 72923 (December 23, 2021) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the 2019–2020 Antidumping Duty Administrative Review of Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See* Memorandum, ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Extension of Deadline for Final Results of Antidumping Duty Administrative Review; 2019–2020,'' dated April 19, 2022.

[4] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value, and Antidumping Duty Order,* 77 FR 73018 (December 7, 2012) (*Order*); *see also Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Final Results of Changed Circumstances Reviews, and Revocation of Antidumping and Countervailing Duty Orders, in Part,* 86 FR 71616–71617 (December 17, 2021) (excluding certain off-grid CSPV). This scope also reflects the USHTS subheadings 8541.42.0010, and 8541.43.0010. which were updated in 2022. The HTSUS subheadings in effect during the POR were 8501.61.0010, 8507.20.80, 8541.40.6015, 8541.40.6025, and 8501.31.8010.

[5] Canadian Solar comprises Canadian Solar International Limited; Canadian Solar Manufacturing (Changshu) Inc.; Canadian Solar Manufacturing (Luoyang) Inc.; CSI Cells Co., Ltd.; CSI Solar Power (China) Inc.; and CSI–GCL Solar Manufacturing (Yancheng) Co., Ltd.

[6] Yingli comprises Shenzhen Yingli New Energy Resources Co., Ltd.; Baoding Jiasheng Photovoltaic Technology Co., Ltd.; Baoding Tianwei Yingli New Energy Resources Co., Ltd.; Beijing Tianneng Yingli New Energy Resources Co., Ltd.; Hainan Yingli New Energy Resources Co., Ltd.; Hengshui Yingli New Energy Resources Co., Ltd.; Lixian Yingli New Energy Resources Co., Ltd.; Tianjin Yingli New Energy Resources Co., Ltd.; and Yingli Energy (China) Company Limited.

[7] *See Preliminary Results* PDM at 5.

our calculation of Jinko's [8] and Risen's [9] (the mandatory respondents) weighted-average dumping margins, changed certain surrogate values, granted BYD (Shangluo) Industrial Co., Ltd. (BYD Shangluo) a separate rate, and updated the weighted-average dumping margin assigned to the companies who are eligible for a separate rate.

Separate Rates

As noted above, we have granted BYD Shangluo, which we denied a separate rate in the *Preliminary Results,* a separate rate. We made no other changes to our preliminary separate rate findings. Therefore, we granted Jinko, Risen, and the eleven other companies/company groups listed in the ''Final Results of Review'' section below separate rate status. However, we have continued to deny separate rate status to all of the companies listed in Appendix II of the *Preliminary Results* notice except BYD Shangluo.

Dumping Margin for Non-Individually Examined Respondents Granted Separate Rate Status

The statute and Commerce's regulations do not address the rate to apply to respondents not selected for individual examination in a non-market economy (NME) administrative review who are eligible for a separate rate. When considering which rate to apply to such respondents, Commerce generally looks to section 735(c)(5) of the Tariff Act of 1930, as amended (the Act), which provides instructions for calculating the all-others rate in an antidumping duty investigation. Section 735(c)(5)(A) of the Act instructs Commerce to base the all-others rate on the estimated weighted-average dumping margins established for the exporters and producers individually investigated, excluding any dumping margins that are zero, *de minimis,* or based entirely on facts available.

Because we calculated final dumping margins for the mandatory respondents Jinko and Risen which are not zero, *de minimis,* or based entirely on facts available, consistent with Commerce's practice and section 735(c)(5)(A) of the Act, we assigned the separate rate recipients a dumping margin equal to the weight average of Jinko's and Risen's final dumping margins. We weight averaged Jinko's and Risen's final dumping margins using the public values of their reported sales of subject merchandise to the United States during the POR.[10]

Final Results of Review

We are assigning the following dumping margins to the firms listed below for the period December 1, 2019, through November 30, 2020:

Producers/exporters	Weighted-average dumping margin (percent)
Jinko Solar Import and Export Co., Ltd./Jinko Solar Co., Ltd./JinkoSolar Technology (Haining) Co., Ltd./Yuhuan Jinko Solar Co., Ltd./Zhejiang Jinko Solar Co., Ltd./Jiangsu Jinko Tiansheng Solar Co., Ltd./JinkoSolar (Chuzhou) Co., Ltd./JinkoSolar (Yiwu) Co., Ltd./JinkoSolar (Shangrao) Co., Ltd	15.71
Risen Energy Co. Ltd./Risen (Wuhai) New Energy Co., Ltd./Zhejiang Twinsel Electronic Technology Co., Ltd./Risen (Luoyang) New Energy Co., Ltd./Jiujiang Shengzhao Xinye Technology Co., Ltd./Jiujiang Shengzhao Xinye Trade Co., Ltd./Ruichang Branch/Risen Energy (HongKong) Co., Ltd./Risen Energy (Changzhou) Co., Ltd./Risen Energy (YIWU) Co., Ltd	8.00
Review-Specific Average Rate Applicable to the Following Companies	
Anji DaSol Solar Energy Science & Technology Co., Ltd	10.24
BYD (Shangluo) Industrial Co., Ltd	10.24
Chint Solar (Zhejiang) Co., Ltd., Chint New Energy Technology (Haining) Co., Ltd., Chint Solar (Jiuquan) Co., Ltd., Chint Solar (Hong Kong) Company Limited	10.24
JA Solar Technology Yangzhou Co., Ltd	10.24
LONGi Solar Technology Co., Ltd	10.24
Shanghai JA Solar Technology Co., Ltd	10.24
Shenzhen Topray Solar Co., Ltd	10.24
Wuxi Suntech Power Co., Ltd	10.24
Wuxi Tianran Photovoltaic Co., Ltd	10.24
Xiamen Yiyusheng Solar Co., Ltd	10.24
Zhejiang Aiko Solar Energy Technology Co., Ltd	10.24

Commerce's policy regarding the conditional review of the China-wide entity applies to this administrative review.[11] Under this policy, Commerce will not review the China-wide entity in an administrative review unless a party specifically requests, or Commerce self-initiates, a review of the entity. Because no party requested a review of the China-wide entity, and Commerce did not self-initiate a review of the entity, the China-wide entity is not under review, and the dumping margin assigned to the China-wide entity (*i.e.,* 238.95 percent) has not changed.[12]

Disclosure

Pursuant to 19 CFR 351.224(b), within five days of the publication of this

[8] We have continued to treat the following companies as a single entity: Jinko Solar Import and Export Co., Ltd.; Jinko Solar Co., Ltd.; JinkoSolar Technology (Haining) Co., Ltd.; Yuhuan Jinko Solar Co., Ltd.; Zhejiang Jinko Solar Co., Ltd.; Jiangsu Jinko Tiansheng Solar Co., Ltd.; JinkoSolar (Chuzhou) Co., Ltd.; JinkoSolar (Yiwu) Co., Ltd.; and JinkoSolar (Shangrao) Co., Ltd. (collectively, Jinko).

[9] We have continued to treat the following companies as a single entity: Risen Energy Co. Ltd.; Risen (Wuhai) New Energy Co., Ltd.; Zhejiang Twinsel Electronic Technology Co., Ltd.; Risen (Luoyang) New Energy Co., Ltd.; Jiujiang Shengzhao Xinye Technology Co., Ltd.; Jiujiang Shengzhao Xinye Trade Co., Ltd.; Ruichang Branch (Ruichang Branch); Risen Energy (HongKong) Co., Ltd. (Risen Hong Kong); Risen Energy (Changzhou) Co., Ltd.; and Risen Energy (YIWU) Co., Ltd. (collectively, Risen).

[10] *See* Memorandum, ''2019–2020 Administrative Review of the Antidumping Duty Order on Crystalline Silicon Photovoltaic Cells, Whether or not Assembled into Modules, from the People's Republic of China: Calculation of the Dumping Margin for Respondents Not Selected for Individual Examination,'' dated concurrently with this notice.

[11] *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, 65969–70 (November 4, 2013).

[12] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2018–2019,* 86 FR 58871 (October 25, 2021).

notice in the **Federal Register**, we will disclose to the parties to this proceeding, the calculations that we performed for these final results of review.

Assessment

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b), Commerce will determine, and U.S. Customs Border and Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise covered by the final results of this review. Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication date of the final results of this review in the **Federal Register**. We intend to instruct CBP to liquidate entries containing subject merchandise exported by the companies under review that we determine in the final results to be part of the China-wide entity at the China-wide entity rate of 238.95 percent.

If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Where merchandise was entered into the United States under the case number of a mandatory respondent in this review during the POR (*i.e.,* entered under the mandatory respondent's cash deposit rate), but the mandatory respondent did not report a corresponding sale or entry in its U.S. sales database, we will instruct CBP to liquidate such entries at the China-wide rate. In addition, for the companies for which we determined that there were no entries, exports, or sales of subject merchandise during the POR, any suspended entries of subject merchandise entered under one of the companies' case numbers during the POR will be liquidated at the China-wide rate.[13]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review in the **Federal Register**. Pursuant to section 751(a)(2)(C) of the Act, for shipments of subject merchandise from the People's Republic of China entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**, the following cash deposits will be required: (1) for the companies/company groups listed in the table in the ''Final Results of Review'' section above, the cash deposit rate will be the rate listed for each company/company group in the table; (2) for previously investigated Chinese and non-Chinese exporters that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (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 previously established for the China-wide entity (*i.e.,* 238.95 percent); and (4) for all non-China 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 the non-Chinese exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties 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.

Administrative Protective Order

This notice also serves as a reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

This determination is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: June 21, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix

Issues and Decision Memorandum Topics List

[13] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011), for a full discussion of this practice.

[FR Doc. 2022–13773 Filed 6–27–22; 8:45 am]
BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC135]

Western Pacific Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting.

SUMMARY: The Western Pacific Fishery Management Council (Council) and NMFS will convene a Western Pacific Stock Assessment Review (WPSAR) of Level 1 and Level 2 Essential Fish Habitat (EFH) Models for the Main Hawaiian Islands gray jobfish, or uku (*Aprion virescens*).

DATES: The WPSAR meeting will be held July 12, 2022 through July 14, 2022. For specific times and agendas, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: *Meeting address:* In person attendance for WPSAR Panelists and participants will be hosted at the Council Office Conference Room, Western Pacific Fishery Management Council, 1164 Bishop St., Suite 1400, Honolulu, HI 96813.

The meeting will be held in a hybrid format with in-person and remote participation (Webex) options available for WPSAR Panelists and participants, with public attendance limited to web conference via Webex. Specific information on joining the meeting, connecting to the web conference and providing oral public comments will be posted on the Council website at *www.wpcouncil.org.* For assistance with the web conference connection, contact the Council office at (808) 522–8220.

FOR FURTHER INFORMATION CONTACT: Kitty M. Simonds, Executive Director, Western Pacific Fishery Management Council; telephone: (808) 522–8220.

SUPPLEMENTARY INFORMATION: The WPSAR meeting will be held on July 12–14, 2022, and run each day from 9 a.m. to 5 p.m. Hawaii Standard Time (HST). Public comment periods will be provided in the agenda. The order in which agenda items are addressed may change. The meetings will run as late as necessary to complete scheduled business.

Agenda for the Western Pacific Stock Assessment Review Meeting

Day 1—Tuesday, July 12, 2022, 9 a.m. to 5 p.m. HST

1. Welcome and Introductions
2. Objectives and Terms of Reference
3. *Overview:* Essential Fish Habitat (EFH) and Habitat Areas of Particular Concern (HAPC)
4. Background Information on MHI Uku
   A. Main Hawaii Islands (MHI) Fisheries & Data Reporting of Uku
   B. Life History and Biology of MHI Uku
   C. Stock Assessment and Status of MHI Uku
5. Fishery Independent Data Sources for MHI Uku
6. Model-based EFH Definitions for the Uku (*Aprion virescens*) in the MHI
   A. Data Sources
   B. Methods
   C. Results and Discussion
7. Spatiotemporal Assessment of Uku (*Aprion virescens*) Density in Shallow MHI Waters, 2010–19
   A. Data Sources
   B. Methods
   C. Results and Discussion
8. Public Comment
9. WPSAR Review Panel Review and Deliberations (closed to the public)

Day 2—Wednesday, July 13, 2022, 9 a.m. to 5 p.m. HST

10. WPSAR Review Panel Discussion with Presenters (morning)
11. WPSAR Review Panel Discussions (closed, afternoon)

Day 3—Thursday, July 14, 2022, 9 a.m. to 5 p.m. HST

12. Continue WPSAR Panel Discussions (closed, morning)
13. WPSAR Panel Report on Uku EFH Review Recommendations (afternoon)
14. Adjourn

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, (808) 522–8220 (voice) or (808) 522–8226 (fax), at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: June 23, 2022.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–13794 Filed 6–27–22; 8:45 am]
BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC130]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The Scientific and Statistical Committee (SSC) of the Mid-Atlantic Fishery Management Council (Council) will hold a meeting.

DATES: The meeting will be held on Monday, July 25, 2022, starting at 10 a.m. and continue through 1 p.m. on Tuesday, July 26, 2022. See **SUPPLEMENTARY INFORMATION** for agenda details.

ADDRESSES: The meeting will be conducted in a hybrid format, with options for both in-person and webinar participation. The meeting will be held at the Baltimore Marriott Waterfront, 700 Aliceanna Street, Baltimore, MD 21202. Details on how to connect to the webinar by computer and by telephone will be available at: *www.mafmc.org/ssc.*

Council address: Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; website: *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: During this meeting, the SSC will review and provide science and research advice on the results from the recently completed Surfclam genetics study. The SSC will make an initial 2023 fishing year acceptable biological catch (ABC) recommendation for *Illex* squid based on the research track stock assessment peer review results and the most recent fishery and survey information. The SSC will also make multi-year (2023–2024) ABC recommendations for Butterfish based on the results of the recently completed management track

stock assessment. The SSC will get an update on recent Council action on the recreational harvest control rule framework. The SSC will review the most recent survey and fishery data and the previously recommended 2023 ABC for Summer Flounder, Scup, Black Sea Bass, and Bluefish. The SSC will also review and provide comments on the draft Northeast Regional Climate Strategy Action Plan. The SSC may take up any other business as necessary.

A detailed agenda and background documents will be made available on the Council's website (*www.mafmc.org*) prior to the meeting.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to Shelley Spedden, (302) 526–5251, at least 5 days prior to the meeting date.

Dated: June 23, 2022.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–13749 Filed 6–27–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC118]

Schedules for Atlantic Shark Identification Workshops and Protected Species Safe Handling, Release, and Identification Workshops

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public workshops.

SUMMARY: Free Atlantic Shark Identification Workshops and Safe Handling, Release, and Identification Workshops will be held in July, August, and September of 2022. Certain fishermen and shark dealers are required to attend a workshop to meet regulatory requirements and to maintain valid permits. Specifically, the Atlantic Shark Identification Workshop is mandatory for all federally permitted Atlantic shark dealers. The Safe Handling, Release, and Identification Workshop is mandatory for vessel owners and operators who use bottom longline, pelagic longline, or gillnet gear, and who have also been issued shark or swordfish limited access permits. Additional free workshops will be conducted later in 2022 and will be announced in a future notice. In addition, NMFS has implemented online recertification workshops for persons who have already taken an in-person training. Information about the online workshops is available on the Atlantic Highly Migratory Species Management Division's website (see **SUPPLEMENTARY INFORMATION**).

DATES: The Atlantic Shark Identification Workshops will be held on July 14, 2022 and September 8, 2022. The Safe Handling, Release, and Identification Workshops will be held on July 8, 2022, August 22, 2022, and September 30, 2022. See **SUPPLEMENTARY INFORMATION** for further details.

ADDRESSES: The Atlantic Shark Identification Workshops will be held in Fort Lauderdale, FL, and Norfolk, VA. The Safe Handling, Release, and Identification Workshops will be held in Gulfport, MS; Vero Beach, FL; and Ronkonkoma, NY. See **SUPPLEMENTARY INFORMATION** for further details on workshop locations.

FOR FURTHER INFORMATION CONTACT: Craig Cockrell by email at *craig.cockrell@noaa.gov* or by phone at 301–427–8503.

SUPPLEMENTARY INFORMATION: Atlantic highly migratory species (HMS) fisheries are managed under the authority of the Atlantic Tunas Convention Act (16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*). The 2006 Consolidated Atlantic HMS Fishery Management Plan and its amendments are implemented by regulations at 50 CFR part 635. Section 635.8 describes the requirements for the Atlantic Shark Identification Workshops and Safe Handling, Release, and Identification Workshops. The workshop schedules, registration information, and a list of frequently asked questions regarding the Atlantic Shark Identification and Safe Handling, Release, and Identification workshops are available online at: *https://www.fisheries.noaa.gov/atlantic-highly-migratory-species/atlantic-shark-identification-workshops* and *https://www.fisheries.noaa.gov/atlantic-highly-migratory-species/safe-handling-release-and-identification-workshops.*

Atlantic Shark Identification Workshops

Since January 1, 2008, Atlantic shark dealers have been prohibited from receiving, purchasing, trading, or bartering for Atlantic sharks unless a valid Atlantic Shark Identification Workshop certificate is on the premises of each business listed under the shark dealer permit that first receives Atlantic sharks (71 FR 58057; October 2, 2006). Dealers who attend and successfully complete a workshop are issued a certificate for each place of business that is permitted to receive sharks. These certificate(s) are valid for 3 years. Thus, certificates that were initially issued in 2019 will expire in 2022. Approximately 193 free Atlantic Shark Identification Workshops have been conducted since October 2008.

Currently, permitted dealers may send a proxy to an Atlantic Shark Identification Workshop. However, if a dealer opts to send a proxy, the dealer must designate a proxy for each place of business covered by the dealer's permit that first receives Atlantic sharks. Only one certificate will be issued to each proxy. A proxy must be a person who is currently employed by a place of business covered by the dealer's permit; is a primary participant in the identification, weighing, and/or first receipt of fish as they are offloaded from a vessel; and who fills out dealer reports. Atlantic shark dealers are prohibited from renewing a Federal shark dealer permit unless a valid Atlantic Shark Identification Workshop certificate for each business location that first receives Atlantic sharks has been submitted with the permit renewal application. Additionally, a copy of a valid dealer or proxy Atlantic Shark Identification Workshop certificate must be in any trucks or other conveyances that are extensions of a dealer's place of business.

Workshop Dates, Times, and Locations

1. July 14, 2022, 12 p.m.–4 p.m., Hampton Inn & Suites, 720 East Cypress Creek Road, Fort Lauderdale, FL 33334.

2. September 8, 2022, 12 p.m.–4 p.m., LaQuinta Inn & Suites Norfolk Airport, 1387 North Military Highway, Norfolk, VA 23502.

Registration

To register for a scheduled Atlantic Shark Identification Workshop, please contact Eric Sander at *ericssharkguide@yahoo.com* or at (386) 852–8588. Pre-registration is highly recommended, but not required.

Registration Materials

To ensure that workshop certificates are linked to the correct permits, participants will need to bring the following specific items to the workshop:

- Atlantic shark dealer permit holders must bring proof that the attendee is an owner or agent of the business (such as articles of incorporation), a copy of the

applicable permit, and proof of identification.

• Atlantic shark dealer proxies must bring documentation from the permitted dealer acknowledging that the proxy is attending the workshop on behalf of the permitted Atlantic shark dealer for a specific business location, a copy of the appropriate valid permit, and proof of identification.

Workshop Objectives

The Atlantic Shark Identification Workshops are designed to reduce the number of unknown and improperly identified sharks reported in the dealer reporting form and increase the accuracy of species-specific dealer-reported information. Reducing the number of unknown and improperly identified sharks will improve quota monitoring and the data used in stock assessments. These workshops will train shark dealer permit holders or their proxies to properly identify Atlantic shark carcasses.

Safe Handling, Release, and Identification Workshops

Since January 1, 2007, shark limited-access and swordfish limited-access permit holders who fish with longline or gillnet gear have been required to submit a copy of their Safe Handling, Release, and Identification Workshop certificate in order to renew either permit (71 FR 58057; October 2, 2006). These certificate(s) are valid for 3 years. Certificates issued in 2019 will expire in 2022. As such, vessel owners who have not already attended a workshop and received a NMFS certificate, or vessel owners whose certificate(s) will expire prior to the next permit renewal, must attend a workshop to fish with, or renew, their swordfish and shark limited-access permits. Additionally, new shark and swordfish limited-access permit applicants who intend to fish with longline or gillnet gear must attend a Safe Handling, Release, and Identification Workshop and submit a copy of their workshop certificate before either of the permits will be issued. Approximately 394 free Safe Handling, Release, and Identification Workshops have been conducted since 2006.

In addition to vessel owners, at least one operator on board vessels issued a limited-access swordfish or shark permit that uses longline or gillnet gear is required to attend a Safe Handling, Release, and Identification Workshop and receive a certificate. Vessels that have been issued a limited-access swordfish or shark permit and that use longline or gillnet gear may not fish unless both the vessel owner and operator have valid workshop certificates onboard at all times. Vessel operators who have not already attended a workshop and received a NMFS certificate, or vessel operators whose certificate(s) will expire prior to their next fishing trip, must attend a workshop to operate a vessel with swordfish and shark limited-access permits on which longline or gillnet gear is used.

Workshop Dates, Times, and Locations

1. July 8, 2022, 9 a.m.–5 p.m., Holiday Inn Gulfport, 9515 Highway 49, Gulfport, MS 39503.

2. August 22, 2022, 9 a.m.–5 p.m., Holiday Inn, 3384 Ocean Drive, Vero Beach, FL 32963.

3. September 30, 2022, 9 a.m.–5 p.m., Courtyard by Marriott, 5000 Express Drive South, Ronkonkoma, NY 11779.

Registration

To register for a scheduled Safe Handling, Release, and Identification Workshop, please contact Angler Conservation Education at (386) 682–0158. Pre-registration is highly recommended, but not required.

Registration Materials

To ensure that workshop certificates are linked to the correct permits, participants will need to bring the following specific items with them to the workshop:

• Individual vessel owners must bring a copy of the appropriate swordfish and/or shark permit(s), a copy of the vessel registration or documentation, and proof of identification;

• Representatives of a business-owned or co-owned vessel must bring proof that the individual is an agent of the business (such as articles of incorporation), a copy of the applicable swordfish and/or shark permit(s), and proof of identification; and

• Vessel operators must bring proof of identification.

Workshop Objectives

The Safe Handling, Release, and Identification Workshops are designed to teach longline and gillnet fishermen the required techniques for the safe handling and release of entangled and/or hooked protected species, such as sea turtles, marine mammals, smalltooth sawfish, Atlantic sturgeon, and prohibited sharks. In an effort to improve reporting, the proper identification of protected species and prohibited sharks will also be taught at these workshops. Additionally, individuals attending these workshops will gain a better understanding of the requirements for participating in these fisheries. The overall goal of these workshops is to provide participants with the skills needed to reduce the mortality of protected species and prohibited sharks, which may prevent additional regulations on these fisheries in the future.

Online Recertification Workshops

NMFS implemented an online option for shark dealers and longline and gillnet fishermen to renew their certificates in December 2021. To be eligible for online recertification workshops, dealers and fishermen need to have previously attended an in-person workshop. Information about the courses is available online at *https://www.fisheries.noaa.gov/atlantic-highly-migratory-species/atlantic-shark-identification-workshops* and *https://www.fisheries.noaa.gov/atlantic-highly-migratory-species/safe-handling-release-and-identification-workshops.*

To access the course please visit: https://hmsworkshop.fisheries.noaa.gov/start.

(Authority: 16 U.S.C. 1801 *et seq.*)

Dated: June 22, 2022.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–13705 Filed 6–27–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC117]

Fisheries of the South Atlantic; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of SEDAR 82 South Atlantic Gray Triggerfish Data Webinar I.

SUMMARY: The SEDAR 82 assessment of the South Atlantic stock of Gray Triggerfish will consist of a data workshop, a series of assessment webinars, and a review workshop. A SEDAR 82 Data Webinar I is scheduled for July 27, 2022.

See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 82 South Atlantic Gray Triggerfish Data Webinar I is scheduled for July 27, 2022, from 10 a.m. to 2 p.m. Eastern. The established times may be adjusted as necessary to

accommodate the timely completion of discussion relevant to the assessment process. Such adjustments may result in the meeting being extended from or completed prior to the time established by this notice.

ADDRESSES: The meeting will be held via webinar. The webinar is open to members of the public. Registration for the webinar is available by contacting the SEDAR coordinator via email at *Kathleen.Howington@safmc.net.*

SEDAR address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405; *www.sedarweb.org.*

FOR FURTHER INFORMATION CONTACT: Kathleen Howington, SEDAR Coordinator, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone: (843) 571–4371; email: *Kathleen.Howington@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions, have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a three-step process including: (1) Data Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data Workshop is a data report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report which describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, Highly Migratory Species Management Division, and Southeast Fisheries Science Center. Participants include: data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion at the SEDAR 82 South Atlantic Gray Triggerfish Data Scoping Webinar I are as follows: discuss available data resources, aging data sources and issues, morphometric data usage, and any other known data issues.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the South Atlantic Fishery Management Council office (see **ADDRESSES**) at least 10 business days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

(Authority: 16 U.S.C. 1801 *et seq.*)

Dated: June 23, 2022.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–13740 Filed 6–27–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC121]

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Scallop Survey Working Group to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Thursday, July 14, 2022, at 9 a.m.

ADDRESSES: This meeting will be held at the Fairfield Inn and Suites, 185 MacArthur Drive, New Bedford, MA 02740; telephone: (774) 634–2009.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Scallop Survey Working Group (SSWG) will receive progress updates to address the Terms of Reference. The group will also review draft SSWG recommendations, SSWG sub-group activities, and timelines for completion of the SSWG report. Other business may be discussed, as necessary.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

(Authority: 16 U.S.C. 1801 *et seq.*)

Dated: June 23, 2022.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–13744 Filed 6–27–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC112]

Fisheries of the Gulf of Mexico; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of SEDAR 75 Shore Mode Topical Working Group recommendations webinar for Gulf of Mexico gray snapper.

SUMMARY: The SEDAR 75 assessment of Gulf of Mexico gray snapper will consist of a series of assessment webinars. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 75 recommendations webinar for the Shore Mode Topical Working Group will be held July 19, 2022, from 1 p.m. until 3 p.m. Eastern. The established times may be adjusted as necessary to accommodate the timely completion of discussion relevant to the assessment process. Such adjustments may result in the meeting being extended from or completed prior to the time established by this notice.

ADDRESSES:

Meeting address: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julie A. Neer at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; (843) 571–4366; email: *Julie.neer@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a multi-step process including: (1) Data Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data Workshop is a data report that compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report that describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, HMS Management Division, and Southeast Fisheries Science Center. Participants include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and NGO's; International experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion in the recommendations webinar are as follows:

Participants will make recommendations on Shore Mode data available for use in the assessment of Gulf of Mexico gray snapper.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 10 business days prior to each workshop.

Note: The times and sequence specified in this agenda are subject to change.

(Authority: 16 U.S.C. 1801 *et seq.*)

Dated: June 23, 2022.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–13739 Filed 6–27–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC110]

Fisheries of the South Atlantic; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of SEDAR 77 HMS Hammerhead Sharks Assessment Webinar II.

SUMMARY: The SEDAR 77 assessment of the Atlantic stock of hammerhead sharks will consist of a stock identification (ID) process, data webinars/workshop, a series of assessment webinars, and a review workshop.

DATES: The SEDAR 77 HMS Hammerhead Sharks Assessment Webinar II has been scheduled for Friday, July 15, 2022, from 11 a.m. until 2 p.m., Eastern Time. The established times may be adjusted as necessary to accommodate the timely completion of discussion relevant to the assessment process. Such adjustments may result in the meeting being extended from or completed prior to the time established by this notice.

ADDRESSES: The meeting will be held via webinar. The webinar is open to members of the public. Registration for the webinar is available by contacting the SEDAR coordinator via email at *Kathleen.Howington@safmc.net.*

SEDAR address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405; *www.sedarweb.org.*

FOR FURTHER INFORMATION CONTACT: Kathleen Howington, SEDAR Coordinator, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone: (843) 571–4371; email: *Kathleen.Howington@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions,

have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a three-step process including: (1) Data Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data Workshop is a data report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report which describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, Highly Migratory Species Management Division, and Southeast Fisheries Science Center. Participants include: data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion at the SEDAR 77 HMS Hammerhead Shark Assessment Webinar II are as follows: discuss any leftover data issues that were not cleared up during the data process, answer any questions that the analysts have, and introduce/discuss model development and model setup.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the South Atlantic Fishery Management Council office (see **ADDRESSES**) at least 5 business days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

(Authority: 16 U.S.C. 1801 *et seq.*)

Dated: June 23, 2022.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–13741 Filed 6–27–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC128]

Atlantic Coastal Fisheries Cooperative Management Act Provisions; General Provisions for Domestic Fisheries; Application for Exempted Fishing Permits

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; request for comments.

SUMMARY: NMFS is reopening the comment period for an Exempted Fishing Permit application. The Exempted Fishing Permit would allow commercial fishing vessels to conduct commercial fishing activities that the regulations would otherwise restrict to expand trials of on-demand fishing gear that uses one or no surface buoys. Regulations under the Magnuson-Stevens Fishery Conservation and Management Act and the Atlantic Coastal Fisheries Cooperative Management Act require publication of this notification to provide interested parties the opportunity to comment on applications for proposed Exempted Fishing Permits.

DATES: Comments must be received on or before July 5, 2022.

ADDRESSES: You may submit written comments by the following method:

- *Email: nmfs.gar.efp@noaa.gov.* Include in the subject line ''NEFSC On-Demand Gear EFP.''
- *Mail:* Michael Pentony, Regional Administrator, NMFS, Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope ''Comments on NEFSC On-Demand Gear EFP.''

FOR FURTHER INFORMATION CONTACT: Laura Deighan, Fishery Management Specialist, *Laura.Deighan@noaa.gov,* (978) 281–9184.

SUPPLEMENTARY INFORMATION: On June 1, 2022, we published a notice soliciting public comment on the EFP application (87 FR 33132). The public comment period was open through June 16, 2022. Given the scope of the proposed project, as well as requests to provide additional information and opportunity to comment, we are reopening the comment period for five days. A full description of the requested exemptions and research plan are available in the original notice and are not repeated here.

This EFP would exempt the participating vessels from the gear marking requirements at 50 CFR 697.21(b)(2) to allow the use of trawls of more than three traps that have one or no surface markers. This EFP would allow up to 100 vessels to trial on-demand lobster gear designed to reduce entanglement risk to protected species, mainly North Atlantic right whales, on up to 10 trawls each. It would allow up to 30 of those vessels to trial gear with no static vertical lines in Atlantic Large Whale Take Reduction Plan (ALWTRP) Restricted Areas and up to 25 to trial grappling for gear with no vertical lines.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: June 22, 2022.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–13684 Filed 6–27–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Notice of Intent To Conduct Scoping and To Prepare a Draft Environmental Impact Statement for the Proposed Hudson Canyon National Marine Sanctuary

Correction

In notice document 2022–12234 beginning on page 34853 in the issue of Wednesday, June 8, 2022, make the following correction:

On page 34853, in the second column, in the last two lines, ''*https://sanctuaries.cnoaa.gov/hudson-canyon/*'' should read ''*https://sanctuaries.noaa.gov/hudson-canyon/*''.

[FR Doc. C1–2022–12234 Filed 6–27–22; 8:45 am]

BILLING CODE 0099–10–D

COURT SERVICES AND OFFENDER SUPERVISION AGENCY

Privacy Act of 1974; System of Records

AGENCY: Court Services and Offender Supervision Agency (CSOSA).

ACTION: Notice of amendment to system of records.

SUMMARY: Pursuant to provisions of the Privacy Act 1974, as amended, the Court Services and Offender Supervision Agency (hereafter ''CSOSA'' or ''Agency'') is issuing a public notice of its intent to update an existing system of records.

DATES: The update became effective in January 2022. SMART has been operational since its inception without the need for amendment. Comments will be accepted until August 8, 2022.

ADDRESSES: Written comments can be sent by any of the following ways:

- *Email: William.Kirkendale@csosa.gov,* Include Amended SORN for SMART in the subject line of the message.
- *U.S. mail or hand-delivery:* CSOSA, ATTN: William Kirkendale, Chief Information Officer, OIT, 800 North Capitol Street NW, Washington, DC 20002. Please include your complete mailing address with your request.

FOR FURTHER INFORMATION CONTACT: William Kirkendale at (202) 220–5426.

SUPPLEMENTARY INFORMATION: This notice serves to update and amend collection, analysis, and maintenance of System of Record for SMART, Supervision and Management Automated Recorded Tracking (hereafter ''SMART''), CSOSA–11, 67 FR 11816, Document number 02–609, maintained by the Agency, as a result of an updated system, System of Record Supervision and Management Automated Record Tracking 21 (SMART21). Revisions include: (1) The system has been updated to reflect current name; (2) The system location has been updated due to CSOSA location; and (3) The system manager contact has been updated.

Court Services and Offender Supervision Agency.

William Kirkendale,

Associate Director, Office of Information Technology.

[FR Doc. 2022–13789 Filed 6–27–22; 8:45 am]

BILLING CODE 3129–04–P

DEPARTMENT OF ENERGY

Basic Energy Sciences Advisory Committee

AGENCY: Office of Science, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a virtual open meeting of the Basic Energy Sciences advisory Committee (BESAC). The Federal Advisory Committee Act requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Thursday, July 14, 2022; 11:00 a.m. to 5:00 p.m.

ADDRESSES: This meeting is open to the public. This meeting will be held digitally via Zoom. Information to participate can be found on the website closer to the meeting date at *https://science.osti.gov/bes/besac/Meetings.*

FOR FURTHER INFORMATION CONTACT: Kerry Hochberger; Office of Basic Energy Sciences; U.S. Department of Energy; Germantown Building, 1000 Independence Avenue SW, Washington, DC 20585; Telephone: (301) 903–7661 or Email: *kerry.hochberger@science.doe.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of this Board is to make recommendations to DOE–SC with respect to the basic energy sciences research program.

Tentative Agenda:

- Call to Order, Introductions, Review of the Agenda
- News from the Office of Science
- News from the Office of Basic Energy Sciences
- Panel Discussion: *BES Early Career*
- News on the Energy Earth Shot Initiative
- Panel Discussion: *Operando Science and Instrumentation*
- Public Comments
- Adjourn

Breaks taken as appropriate.

Public Participation: The meeting is open to the public. A webcast of this meeting will be available. Please check the website below for updates and information on how to view the meeting. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. If you would like to make oral statements regarding any of the items on the agenda, you should contact Kerry Hochberger at *kerry.hochberger@science.doe.gov.* You must make your request for an oral statement at least five business days before the meeting. Reasonable provisions will be made to include the scheduled oral statements on the agenda. The Chairperson of the Committee will conduct the meeting to facilitate the orderly conduct of business. Public comment will follow the 10-minute rule. Information about the committee can be found at: *https://science.osti.gov/bes/besac.*

Minutes: The minutes of this meeting will be available for public review on the U.S. Department of Energy's Office of Basic Energy Sciences website at: *https://science.osti.gov/bes/besac/Meetings.*

Signed in Washington, DC, on June 22, 2022.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2022–13693 Filed 6–27–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Savannah River Site

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Savannah River Site. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES:

Monday, July 25, 2022; 1:00 p.m.–4:30 p.m.

Tuesday, July 26, 2022; 9:00 a.m.–4:30 p.m.

ADDRESSES: DoubleTree Hotel, 2651 Perimeter Parkway, Augusta, GA 30909.

The meeting will also be streamed on YouTube, no registration is necessary; links for the livestream can be found on the following website: *https://cab.srs.gov/srs-cab.html.*

FOR FURTHER INFORMATION CONTACT: Amy Boyette, Office of External Affairs, U.S. Department of Energy (DOE), Savannah River Operations Office, P.O. Box A, Aiken, SC 29802; Phone: (803) 952–6120; or Email: *amy.boyette@srs.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda:

Monday, July 25, 2022:

Chair Update

Agenda Review
Agency Updates
Subcommittee Updates:
- Administrative & Outreach Subcommittee
- Facilities Disposition & Site Remediation Subcommittee
- Nuclear Materials Subcommittee
- Waste Management Subcommittee

Presentations:
- Savannah River Site Archaeology Program
- Justice 40

Public Comments
Board Business
- Discussion/Closure of Recommendation 370, Revise the Member Appointment Process, 6/28/2021

Tuesday, July 26, 2022:
Agenda Review
Presentations:
- Lower Three Runs Integrator Operable Unit Overview
- Savannah River Site Spent Nuclear Fuel Receipts and Storage
- Savannah River National Laboratory
- Defense Waste Processing Facility
- DOE 3013 Container Program
- Plutonium Storage and Down Blend Program
- Environmental Protection Agency and South Carolina Department of Health and Environmental Control Oversight Programs

Public Comments
Board Business, Voting

Public Participation: The meeting is open to the public. It will be held strictly following COVID–19 precautionary measures. To provide a safe meeting environment, seating may be limited; attendees should register for in-person attendance by sending an email to *srscitizensadvisoryboard@srs.gov* no later than 4:00 p.m. ET on Thursday, July 21, 2022. The EM SSAB, Savannah River Site, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Amy Boyette at least seven days in advance of the meeting at the telephone number listed above. Written statements may be filed with the Board via email either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should submit their request to *srscitizensadvisoryboard@srs.gov.* Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. Comments will be accepted after the meeting, by no later than 4:00 p.m. ET on Monday, August 1, 2022. Please submit comments to *srscitizensadvisoryboard@srs.gov.* The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make oral public comments will be provided a maximum of five minutes to present their comments. Individuals wishing to submit written public comments should email them as directed above.

Minutes: Minutes will be available by emailing or calling Amy Boyette at the email address or telephone number listed above. Minutes will also be available at the following website: *https://cab.srs.gov/srs-cab.html.*

Signed in Washington, DC, on June 22, 2022.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2022–13694 Filed 6–27–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: U.S. Department of Energy.

ACTION: Notice and request for comments.

SUMMARY: The Department of Energy (DOE), pursuant to the Paperwork Reduction Act of 1995, intends to extend for three years, an information collection request with the Office of Management and Budget (OMB).

DATES: Comments regarding this proposed information collection must be received on or before July 28, 2022. If you anticipate any difficulty in submitting comments within that period, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section as soon as possible.

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: John Walsh, Office of Talent Management, Office of the Chief Human Capital Officer, U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585–1615; (202) 287–5774; *john.walsh@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the extended 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, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

This information collection request contains:

(1) *OMB No.:* 1910–5193.

(2) *Information Collection Request Titled:* DOE Applicant Portal;

(3) *Type of Review:* Extension;

(4) *Purpose:* The Department of Energy (DOE) will collect two broad types of data: Application Data and Demographic Data. Application Data will include a resume and information about a candidate's contact information, education, work experience, and work interests. DOE will use this information to evaluate an individual's qualifications for employment opportunities in support of the Infrastructure Investment and Jobs Act (IIJA) of 2021, Public Law 117–58 and other direct-hire authorities and to refer potential candidates to relevant application platforms. The Demographic Data requested is strictly voluntary. It will be used to evaluate agency marketing and outreach strategies to expand both the size and diversity of the applicant pool and assess the aggregate diversity of the applicant pool as candidates move through the evaluation process. Potential candidates are the most likely respondents to the Public Notice.

(5) *Annual Estimated Number of Respondents:* 35,000.

(6) *Annual Estimated Number of Total Responses:* 35,000.

(7) *Annual Estimated Number of Burden Hours:* 5,845.

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $340,121.

Statutory Authority: DOE is authorized to collect the information pursuant to its direct hire authorities, including Section 301 of the Infrastructure Investment and Jobs Act (IIJA) of 2021, Public Law 117–58; 5 CFR 337.201; and Office of Personnel Management GW–007, *Direct Hire Authorities* (October 11, 2018), for Scientific, Technical, Engineering, and

Mathematics (STEM) positions. DOE is using existing hiring authorities, including government-wide direct hiring authorities, to identify potential candidates for positions. This information will be collected and maintained under the Privacy Act System of Records Notice OPM/GOVT–5, *Recruiting, Examining, and Placement Records.,* 79 FR 16834 (March 26, 2014), with a modification published in 80 FR 74815 (November 30, 2015) and OPM/GOVT–7 Applicant Race, Sex, National Origin, and Disability Status Records, 71 FR 35351 (June 19, 2006), amended 80 FR 74815 (Nov. 30, 2015).

Signing Authority

This document of the Department of Energy was signed on June 22, 2022, by Erin Moore, Chief Human Capital Officer, Office of the Chief Human Capital Officer, 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 June 23, 2022.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2022–13748 Filed 6–27–22; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2021–0647; FRL–9973–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NSPS for Storage Vessels for Petroleum Liquids for Which Construction, Reconstruction or Modification Commenced After June 11, 1973 and Prior to May 19, 1978 (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NSPS for Storage Vessels for Petroleum Liquids for Which Construction, Reconstruction or Modification Commenced After June 11, 1973 and Prior to May 19, 1978 (EPA ICR Number 1797.09, OMB Control Number 2060–0442), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently-approved through June 30, 2022. Public comments were previously requested, via the **Federal Register**, on February 8, 2021, during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before July 28, 2022.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2020–0647, online using *www.regulations.gov* (our preferred method) or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 2821T, 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.

Submit written comments and recommendations to OMB for the proposed information collection 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: Muntasir Ali, Sector Policies and Program Division (D243–05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–0833; email address: *ali.muntasir@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 *https://www.regulations.gov,* or in person, at the EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: The New Source Performance Standards (NSPS) for Storage Vessels for Petroleum Liquids for Which Construction, Reconstruction or Modification Commenced After June 11, 1973 and Prior to May 19, 1978 (40 CFR part 60, subpart K) apply to existing facilities for which construction, reconstruction, or modification commenced after June 11, 1973 and prior to May 19, 1978 that store petroleum liquids in storage vessels with a storage capacity greater than 151,416 liters (40,000 gallons), including: storage vessels with capacity greater than 151,416 liters (40,000 gallons), but not exceeding 246,052 liters (65,000 gallons). In general, all NSPS standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance and are required of all affected facilities subject to NSPS.

Form Numbers: None.

Respondents/affected entities: Owners and operators of storage vessels subject to 40 CFR part 60, subpart K.

Respondent's obligation to respond: Mandatory (40 CFR part 60, subpart K)

Estimated number of respondents: 281 (total).

Frequency of response: Occasionally.

Total estimated burden: 1,310 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $154,000 (per year), which includes $0 for annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: The increase in burden from the most-recently approved ICR is due to an adjustment. The previously approved ICRs (1797.08, 1797.07) relied on information from the 2011 Petroleum Refinery ICR for estimates of facilities with storage tanks subject to 40 CFR part 60, subpart K, which was the best source of information at that time. However, this ICR updates the number

of facilities based on data from EPA's ECHO database, which tracks a total of 281 refineries, terminals, and other facilities that report information under 40 CFR part 60, subpart K. This estimate is a more-recent estimate of affected sources and is similar to those estimates conducted in prior ICRs (*e.g.,* 1797.06) and reflects the Agency's best knowledge of actual subject entities. However, we expect this number may be lower as facilities that modify tanks initially subject to subpart K would become subject to other regulations, *e.g.,* 40 CFR part 60, subpart Kb. Finally, there is no change in both capital/startup and O&M costs compared to the prior ICR renewal.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2022–13756 Filed 6–27–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2022–0132; FRL–9411–03–OCSPP]

Certain New Chemicals; Receipt and Status Information for May 2022

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is required under the Toxic Substances Control Act (TSCA) to make information publicly available and to publish information in the **Federal Register** pertaining to submissions under TSCA, including notice of receipt of a Premanufacture notice (PMN), Significant New Use Notice (SNUN) or Microbial Commercial Activity Notice (MCAN), including an amended notice or test information; an exemption application (Biotech exemption); an application for a test marketing exemption (TME), both pending and/or concluded; a notice of commencement (NOC) of manufacture (including import) for new chemical substances; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review. This document covers the period from 05/01/2022 to 05/31/2022.

DATES: Comments identified by the specific case number provided in this document must be received on or before July 28, 2022.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2022–0132, and the specific case number for the chemical substance related to your comment, through the *Federal eRulemaking Portal* at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Jim Rahai, Project Management and Operations Division (MC 7407M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–8593; email address: *rahai.jim@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What action is the Agency taking?

This document provides the receipt and status reports for the period from 05/01/2022 to 05/31/2022. The Agency is providing notice of receipt of PMNs, SNUNs, and MCANs (including amended notices and test information); an exemption application under 40 CFR part 725 (Biotech exemption); TMEs, both pending and/or concluded; NOCs to manufacture a new chemical substance; and a periodic status report on new chemical substances that are currently under EPA review or have recently concluded review.

EPA is also providing information on its website about cases reviewed under the amended TSCA, including the section 5 PMN/SNUN/MCANs and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCANs notices on its website at: *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices.* This information is updated on a weekly basis.

B. What is the Agency's authority for taking this action?

Under the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 *et seq.,* a chemical substance may be either an ''existing'' chemical substance or a ''new'' chemical substance. Any chemical substance that is not on EPA's TSCA Inventory of Chemical Substances (TSCA Inventory) is classified as a ''new chemical substance,'' while a chemical substance that is listed on the TSCA Inventory is classified as an ''existing chemical substance.'' (See TSCA section 3(11).) For more information about the TSCA Inventory please go to: *https://www.epa.gov/tsca-inventory.*

Any person who intends to manufacture (including import) a new chemical substance for a non-exempt commercial purpose, or to manufacture or process a chemical substance in a non-exempt manner for a use that EPA has determined is a significant new use, is required by TSCA section 5 to provide EPA with a PMN, MCAN, or SNUN, as appropriate, before initiating the activity. EPA will review the notice, make a risk determination on the chemical substance or significant new use, and take appropriate action as described in TSCA section 5(a)(3).

TSCA section 5(h)(1) authorizes EPA to allow persons, upon application and under appropriate restrictions, to manufacture or process a new chemical substance, or a chemical substance subject to a significant new use rule (SNUR) issued under TSCA section 5(a)(2), for ''test marketing'' purposes, upon a showing that the manufacture, processing, distribution in commerce, use, and disposal of the chemical will not present an unreasonable risk of injury to health or the environment. This is referred to as a test marketing exemption, or TME. For more information about the requirements applicable to a new chemical go to: *https://www.epa.gov/oppt/newchems.*

Under TSCA sections 5 and 8 and EPA regulations, EPA is required to publish in the **Federal Register** certain information, including notice of receipt of a PMN/SNUN/MCANs (including amended notices and test information); an exemption application under 40 CFR part 725 (biotech exemption); an application for a TME, both pending and concluded; NOCs to manufacture a new chemical substance; and a periodic status report on the new chemical substances that are currently under EPA review or have recently concluded review.

C. Does this action apply to me?

This action provides information that is directed to the public in general.

D. Does this action have any incremental economic impacts or paperwork burdens?

No.

E. What should I consider as I prepare my comments for EPA?

1. *Submitting confidential business information (CBI).* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/comments.html.*

II. Status Reports

In the past, EPA has published individual notices reflecting the status of TSCA section 5 filings received, pending or concluded. In 1995, the Agency modified its approach and streamlined the information published in the **Federal Register** after providing notice of such changes to the public and an opportunity to comment (See the **Federal Register** of May 12, 1995, (60 FR 25798) (FRL–4942–7). Since the passage of the Lautenberg amendments to TSCA in 2016, public interest in information on the status of section 5 cases under EPA review and, in particular, the final determination of such cases, has increased. In an effort to be responsive to the regulated community, the users of this information, and the general public, to comply with the requirements of TSCA, to conserve EPA resources and to streamline the process and make it more timely, EPA is providing information on its website about cases reviewed under the amended TSCA, including the section 5 PMN/SNUN/MCANs and exemption notices received, the date of receipt, the final EPA determination on the notice, and the effective date of EPA's determination for PMN/SNUN/MCANs notices on its website at: *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices.* This information is updated on a weekly basis.

III. Receipt Reports

For the PMN/SNUN/MCANs that have passed an initial screening by EPA during this period, Table I provides the following information (to the extent that such information is not subject to a CBI claim) on the notices screened by EPA during this period: The EPA case number assigned to the notice that indicates whether the submission is an initial submission, or an amendment, a notation of which version was received, the date the notice was received by EPA, the submitting manufacturer (*i.e.,* domestic producer or importer), the potential uses identified by the manufacturer in the notice, and the chemical substance identity.

As used in each of the tables in this unit, (S) indicates that the information in the table is the specific information provided by the submitter, and (G) indicates that this information in the table is generic information because the specific information provided by the submitter was claimed as CBI. Submissions which are initial submissions will not have a letter following the case number. Submissions which are amendments to previous submissions will have a case number followed by the letter ''A'' (*e.g.* P–18–1234A). The version column designates submissions in sequence as ''1'', ''2'', ''3'', etc. Note that in some cases, an initial submission is not numbered as version 1; this is because earlier version(s) were rejected as incomplete or invalid submissions. Note also that future versions of the following tables may adjust slightly as the Agency works to automate population of the data in the tables.

TABLE I—PMN/SNUN/MCANS APPROVED * FROM 05/01/2022 TO 05/31/2022

Case No.	Version	Received date	Manufacturer	Use	Chemical substance
P–19–0141A	8	05/05/2022	CBI	(S) For use in metal treatment coatings for lubrication and corrosion protection.	(S) Phosphoric Acid, manganese(2+) salt (2:3);(S) Phosphoric acid, manganese(2+) salt (4:5).
P–21–0195	4	05/04/2022	CBI	(G) Primary component of retail consumer product for animals.	(S) Corn, germ, meal.
P–21–0196A	2	05/25/2022	CBI	(S) Additive for use in battery electrolyte formulations.	(G) Oxathiole, oxide.
P–21–0216A	3	05/22/2022	LG Chem America, Inc	(G) Additive in electrode materials, plastics.	(G) Multi-walled carbon nanotubes.
P–21–0217A	3	05/22/2022	LG Chem America, Inc	(G) Additive in electrode materials, thermoplastics and Component in electrodes.	(G) Multi-walled carbon nanotubes.
P–22–0014	3	05/22/2022	CBI	(G) Precursor	(G) sodium bis(chloropropanediol) phosphate.
P–22–0074	2	04/26/2022	Wilbur Ellis	(G) Agricultural chemical	(S) Phosphonic acid, manganese(2+) salt (1:1).
P–22–0075	2	05/11/2022	Elantas pdg, Inc	(S) Isolated intermediate used as a monomer in the production of a monomer free unsaturated polyester resin.	(S) 1H-Isoindole-1,3(2H)-dione, 3a,4,7,7a-tetrahydro-2-(2-hydroxyethyl)-.
P–22–0077	2	05/24/2022	CBI	(G) Chemical Intermediate	(G) magnesium salt of alkyl substituted hexanol.
P–22–0078	2	04/28/2022	CBI	(S) Dispersing agent	(G) Oxirane, 2-methyl-, polymer with oxirane, mono-isoalkyl ethers, phosphates, salt.
P–22–0078A	3	05/16/2022	CBI	(S) Dispersing agent for pesticide formulators.	(G) Oxirane, 2-methyl-, polymer with oxirane, mono-isoalkyl ethers, phosphates, salt.

TABLE I—PMN/SNUN/MCANS APPROVED * FROM 05/01/2022 TO 05/31/2022—Continued

Case No.	Version	Received date	Manufacturer	Use	Chemical substance
P–22–0078A	4	05/17/2022	CBI	(S) Dispersing agent for pesticide formulators.	(G) Oxirane, 2-methyl-, polymer with oxirane, mono-isoalkyl ethers, phosphates, salt.
P–22–0079	4	05/17/2022	Galata Chemicals, LLC	(S) Stabilizer for PVC compounds	(G) Pyridine carboxylate aliphatic diester.
P–22–0080	2	04/28/2022	Huntsman International, LLC	(S) As an industrial intermediate used in the manufacture of polyamides as a monomer.	(S) Poly(oxy-1,2-ethanediyl), alpha,alpha′-(iminodi-2,1-ethanediyl)bis[omega-(2-aminoethoxy)-;(S) Poly(oxy-1,2-ethanediyl), alpha-(2-aminoethyl)-omega-(2-aminoethoxy)-.
P–22–0080A	3	05/19/2022	Huntsman International, LLC	(S) As an industrial intermediate used in the manufacture of polyamides as a monomer.	(S) Poly(oxy-1,2-ethanediyl), ,′-(iminodi-2,1-ethanediyl)bis[-(2-aminoethoxy)-;(S) Poly(oxy-1,2-ethanediyl), -(2-aminoethyl)--(2-aminoethoxy)-.
P–22–0081	2	05/03/2022	CBI	(S) Light and peroxide cured adhesives, Component of formulation for 3D printing with stereolithography process. (G) Component of light cured adhesives.	(S) 1,3-Propanediol,2,2-dimethyl-, polymer with alpha-hydro-omega-hydroxypoly(oxy-1,4-butanediyl) and 1,1-methylenebis[4-isocyanatocyclohexane], 2-hydroxyethyl methacrylate-blocked.;(S) 1,4-Cyclohexanedimethanol, polymer with 2,2-dimethyl-1,3-Propanediol,alpha-hydro-omega-hydroxypoly(oxy-1,4-butanediyl) and 1,1-methylenebis[4-isocyanatocyclohexane], 2-hydroxyethyl methacrylate-blocked;(S) 1,4-cyclohexanedimethanol, polymer with alpha-hydro-omega-hydroxypoly(oxy-1,4-butanediyl) and 1,1-methylenebis[4-isocyanatocyclohexane], 2-hydroxyethyl methacrylate-blocked.;(S) poly(oxy-1,4-butanediyl), alpha-hydro-omega-hydroxy-polymer with 1,1-methylenebis[4-isocyanatocyclohexane], 2-hydroxyethyl methacrylate-blocked.
P–22–0083	2	05/03/2022	CBI	(G) Perfume	(S) Oils, sandalwood, santalene synthase-modified Rhodobacter sphaeroides-fermented, from D-Glucose, oxidized.
P–22–0083A	3	05/13/2022	CBI	(G) Perfume	(S) Oils, sandalwood, santalene synthase-modified Rhodobacter sphaeroides-fermented, from D-Glucose, oxidized.
P–22–0084	1	04/27/2022	CBI	(G) Performance additive	(G) Diallyldimethylammonium chloride, polymer with acrylic acid and methacrylic acid derivatives.
P–22–0085	1	04/29/2022	CBI	(S) Site limited Intermediate to be further reacted into final product.	(S) Ethane, 1,2-dibromo-1,1-difluoro-.
P–22–0086	2	05/11/2022	SHIN–ETSU Microsi	(G) Contained use for microlithography for electronic device manufacturing.	(G) Phenoxathiinium, 10-phenyl-, 5-alkyl-2-alkyl-4-(2,4,6-substituted tri-carbo polycycle, hetero-acid)benzenesulfonate (1:1).
P–22–0087	1	05/03/2022	Hubergroup	(S) Binder for energy-curing printing inks	(S) Fatty acids, C18-unsatd., dimers, polymers with acrylic acid, bisphenol A, epichlorohydrin, oleic acid, 2,2′-[oxybis(methylene)]bis[2-ethyl-1,3-propanediol] and phthalic anhydride.
P–22–0088	1	05/03/2022	Hubergroup	(S) Binder for energy-curing printing inks	(S) Fatty acids, C18-unsatd., dimers, polymers with acrylic acid, bisphenol A, epichlorohydrin, oleic acid, pentaerythritol and phthalic anhydride.
P–22–0089	4	05/10/2022	Allnex USA, Inc	(S) UV Cured resin for dry toner printing	(G) Carboxylic acid substituted carbomonocycles, polymer with dialkylalkanediol and alkanediol, hydroxyalkyl-oxo-alkenyl)oxy]alkyl ester.
P–22–0090	1	05/06/2022	CBI	(G) Perfume (G) Perfume	(S) 4,8,11-Dodecatrienal.
P–22–0091	4	05/10/2022	Allnex USA, Inc.	(S) UV Cured resin for dry toner printing	(G) Alkanol, polymer with isocyanato-(isocyanatoalkyl)-trialkylcarbomonocycle, alkylene glycol monoacrylate-blocked.
P–22–0092	2	05/12/2022	CBI	(G) Coating material	(G) Ferrous lithiophilite carbide.
P–22–0094	2	05/20/2022	CBI	(G) Contained use as a sputtering material.	(S) Cadmium tin oxide (Cd2SnO4).
P–22–0095	1	05/18/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates.
P–22–0096	1	05/18/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates.

TABLE I—PMN/SNUN/MCANS APPROVED * FROM 05/01/2022 TO 05/31/2022—Continued

Case No.	Version	Received date	Manufacturer	Use	Chemical substance
P–22–0097	1	05/18/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates.
P–22–0098	1	05/18/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates.
P–22–0099	1	05/18/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates.
P–22–0100	1	05/18/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates.
P–22–0101	1	05/18/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts.
P–22–0101A	2	05/23/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts.
P–22–0102	1	05/18/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts.
P–22–0102A	2	05/23/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts.
P–22–0103	1	05/18/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts.
P–22–0103A	2	05/23/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts.
P–22–0104	1	05/18/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts.
P–22–0104A	2	05/23/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts.
P–22–0105	1	05/18/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts.
P–22–0105A	2	05/23/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts.
P–22–0106	1	05/18/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts.
P–22–0106A	2	05/23/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts.
P–22–0107	1	05/18/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts.
P–22–0107A	2	05/23/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts.
P–22–0108	1	05/18/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts.
P–22–0108A	2	05/23/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts.
P–22–0109	1	05/18/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts.
P–22–0109A	2	05/23/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts.
P–22–0110	1	05/18/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts.
P–22–0110A	2	05/23/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts.
P–22–0111	1	05/18/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts.
P–22–0111A	2	05/23/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts.

TABLE I—PMN/SNUN/MCANS APPROVED * FROM 05/01/2022 TO 05/31/2022—Continued

Case No.	Version	Received date	Manufacturer	Use	Chemical substance
P–22–0112	1	05/18/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts.
P–22–0112A	2	05/23/2022	Locus Fermentation Solutions	(G) Surfactant for consumer, industrial, commercial, applications.	(G) Glycolipids, sophorose-contg., yeast-fermented, from glycerides and carbohydrates, salts.
SN–16–0013A ..	4	05/17/2022	CBI	(G) Surfactant	(G) Polyfluorinated alkyl quaternary ammonium chloride.
SN–20–0003A ..	9	05/13/2022	CBI	(S) An anionic fluorosurfactant used in firefighting foam concentrates such as AFFF (Aqueous Film Forming Foam) and AR–AFFF (Alcohol Resistant Aqueous Fim Forming Foam).	(S) 1-Propanesulfonic acid, 2-methyl-2-[[1-oxo-3-[(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)thio]propyl]amino]-, sodium salt (1:1).
SN–22–0004	1	04/29/2022	HPC Holdings, Inc	(S) Carrier Fluid for coating-type vapor degreaser, process solvent (Closed Systems).	(S) Propane, 1,1,1,3,3,3-hexafluoro-2-methoxy-.
SN–22–0005	1	05/18/2022	CBI	(G) Dispersant polymer for coatings	(G) Phenol-formaldehyde polymer with amino-oxirane copolymer and nitrobenzoates.

* The term 'Approved' indicates that a submission has passed a quick initial screen ensuring all required information and documents have been provided with the submission prior to the start of the 90 day review period, and in no way reflects the final status of a complete submission review.

In Table II of this unit, EPA provides the following information (to the extent that such information is not claimed as CBI) on the NOCs that have passed an initial screening by EPA during this period: The EPA case number assigned to the NOC including whether the submission was an initial or amended submission, the date the NOC was received by EPA, the date of commencement provided by the submitter in the NOC, a notation of the type of amendment (*e.g.,* amendment to generic name, specific name, technical contact information, etc.) and chemical substance identity.

TABLE II—NOCS APPROVED * FROM 05/01/2022 TO 05/31/2022

Case No.	Received date	Commencement date	If amendment, type of amendment	Chemical substance
J–21–0020	05/18/2022	05/02/2022	N	(G) Cinderbio-14057 protease.
J–21–0021	05/18/2022	04/29/2022	N	(G) Cinderbio-14624 protease.
J–21–0022	05/18/2022	04/22/2022	N	(G) Cinderbio-23726 protease.
J–21–0023	05/18/2022	04/27/2022	N	(G) Cinderbio-23117 esterase/lipase.
J–21–0024	05/18/2022	04/15/2022	N	(G) Cinderbio-13366 cellulase/xylanase.
J–21–0025	05/18/2022	04/20/2022	N	(G) Cinderbio-13184 amylase.
P–04–0856A	05/11/2022	11/02/2016	Amended generic name	(G) Long chain alkyl benzene sulfonic acids.
P–13–0289A	05/17/2022	06/13/2018	Amended generic name	(G) Alkanoic acid, tetramethyl-sec amino-heteromonocyclic ester.
P–15–0017A	05/05/2022	06/16/2017	Amended generic name	(G) Iron alkylenediaminehydroxyacetate sulfophonic acid.
P–16–0514A	05/12/2022	01/16/2019	Amended generic name	(G) Nickel, cobalt mixed metal oxide.
P–17–0332A	05/13/2022	11/20/2018	Amended generic name	(G) Benzenesulfonic acid, 2,2′-(1,2-ethenediyl)bis[[[(hydroxyalkyl)amino]-(arylamino)-triazinyl]amino]-, n-(hydroxyalkyl).
P–17–0354A	05/13/2022	02/04/2019	Withdrew CBI claim	(S) 4-(fluorodimethylsilyl)-butanenitrile.
P–18–0160A	05/18/2022	02/12/2020	Amended generic name	(G) Heteropolycyclic, halo substituted alkyl substituted-diaromatic amino substituted carbomonocycle, halo substituted alkyl substituted heteropolycyclic, tetraphenylborate (1:1).
P–19–0028A	05/11/2022	08/05/2021	Amended generic name	(G) Alkyl salicylate, calcium salts.
P–20–0084	05/13/2022	04/14/2022	N	(G) 2-propenoic acid, 2-methyl, 2-(dimethylamino)ethyl ester, polymers with 2-(c16–18-acylamino)ethyl acrylate and hydroxyalkyl acrylate, acetates (salts).
P–20–0172	05/11/2022	04/12/2022	N	(G) Glycerin, alkoxylated alkyl acid esters.
P–21–0063A	05/11/2022	11/29/2021	Amended generic name	(G) Pyrazole-polycarboxylic acid, polyhaloaryl-polyhydroalkyl-polyalkyl ester.
P–21–0186A	05/11/2022	01/18/2022	Amended generic name	(G) Glycerin, polyalkyl glycol ethers alkyl acid esters.

* The term 'Approved' indicates that a submission has passed a quick initial screen ensuring all required information and documents have been provided with the submission.

In Table III of this unit, EPA provides the following information (to the extent such information is not subject to a CBI claim) on the test information that has been received during this time period: The EPA case number assigned to the test information; the date the test information was received by EPA, the type of test information submitted, and chemical substance identity.

TABLE III—TEST INFORMATION RECEIVED FROM 05/01/2022 TO 05/31/2022

Case No.	Received date	Type of test information	Chemical substance
P–14–0712	05/16/2022	Polychlorinated Dibenzodioxins and Polychlorinated Dibenzofurans Testing.	(S) Waste plastics, pyrolyzed, C5–55 fraction.
P–16–0462	05/15/2022	Metals Analysis for Quarter 1 and Quarter 2 2022	(G) Ash (residues), reaction products with tetraethoxydioxa-polyheteroatom-disilaalkane.
P–16–0543	05/10/2022	Exposure Monitoring Report	(G) Halogenophosphoric acid metal salt.
P–18–0016	05/09/2022	Dissociation Constant Determination Study	(G) Aromatic sulfonium tricyclo fluoroalkyl sulfonic acid salt.
P–20–0042	05/09/2022	Dissociation Constant Determination Study	(G) Sulfonium, trisaryl-, 7,7-dialkyl-2-heteropolycyclic -1-alkanesulfonate (1:1).
P–20–0042	05/09/2022	Dissociation Constant Determination Study	(G) Sulfonium, trisaryl-, 7,7-dialkyl-2-heteropolycyclic -1-alkanesulfonic acid (1:1).
P–21–0180	05/09/2022	Dissociation Constant Determination Study	(G) Sulfonium, (halocarbomonocycle)diphenyl-, salt with 1-heterosubstituted-2-methylalkyl trihalobenzoate (1:1).
P–21–0180	05/09/2022	Dissociation Constant Determination Study	(G) Sulfonium, (heterosubstitutedphenyl)diphenyl-, salt with 1-heterosubstituted-2-methylalkyl trisubstitutedbenzoate (1:1).
P–22–0021	05/18/2022	Acute Fish Testing; Ready Biodegradability Testing (OECD Test Guideline 301); Skin Sensitizaiton Testing (OECD Test Guideline 406); Testing Summary Information; In Vitro Mammalian Chromosome Aberration Testing (OECD Test Guideline 473); Mammalian Erythrocyte Micronucleus Testing (OECD Test Guideline 474); Acute Oral Toxicity Testing (OECD Test Guideline 401, 420, 423, 425); Acute Dermal Irriation Testing (OECD Test Guideline 404); Acute Eye Irritation Testing (OECD Test Guideline 405).	(G) Alkylphosphonic acid, calcium salt.

If you are interested in information that is not included in these tables, you may contact EPA's technical information contact or general information contact as described under **FOR FURTHER INFORMATION CONTACT** to access additional non-CBI information that may be available.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: June 15, 2022.

Pamela Myrick,

Director, Project Management and Operations Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2022–13779 Filed 6–27–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2021–0118; FRL–9977–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Mercury Cell Chlor-Alkali Plants (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), NESHAP for Mercury Cell Chlor-Alkali Plants (EPA ICR Number 2046.12, OMB Control Number 2060–0542), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through June 30, 2022. Public comments were previously requested, via the **Federal Register**, on April 13, 2021 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before July 28, 2022.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2021–0118, online using *www.regulations.gov* (our preferred method) or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 2821T, 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.

Submit written comments and recommendations to OMB for the proposed information collection 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: Muntasir Ali, Sector Policies and Program Division (D243–05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–0833; email address: *ali.muntasir@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 *https://www.regulations.gov,* or in person at the EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: Owners and operators of mercury cell chlor-alkali plants are required to comply with reporting and record keeping requirements for the General Provisions (40 CFR part 63, subpart A), as well as for the applicable specific standards in 40 CFR part 63, subpart IIIII. This includes submitting initial notifications, performance tests and periodic reports and results, and maintaining records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These reports are used by EPA to determine compliance with these standards.

Form Numbers: None.

Respondents/affected entities: Mercury cell chlor-alkali plants.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart IIIII).

Estimated number of respondents: 1 (total).

Frequency of response: Semiannually.

Total estimated burden: 1,880 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $231,000 (per year), which includes $8,200 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: There is a decrease in burden from the most-recently approved ICR as currently identified in the OMB Inventory of Approved Burdens. This is due to a decrease in the number of sources subject to the rule. Data gathered by EPA in the development of the proposed Residual Risk and Technology Review for 40 CFR part 63, subpart IIIII (86 FR 1362, January 8, 2021) indicates that there is only one source subject to this rule. The regulations have been revised in the past three years to add electronic reporting requirements, but it is assumed that there is no additional burden associated with the requirements, which consist of an upload of a currently required notification in portable document format (PDF). There is no change in capital/startup costs, as there is no change in the number of new facilities, which remains at zero. Due to the decrease in the number of facilities subject to the rule, total O&M costs have decreased from the previous ICR.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2022–13770 Filed 6–27–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OA–2019–0296; FRL–OP–OFA–22]

Proposed Information Collection Request; Comment Request; Procedures for Implementing the National Environmental Policy Act and Assessing the Environmental Effects Abroad of EPA Actions (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency is planning to submit an information collection request (ICR), ''Procedures for Implementing the National Environmental Policy Act and Assessing the Environmental Effects Abroad of EPA Actions'' (EPA ICR No. 2243.08, OMB Control No. 2020–0033) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA). Before doing so, the 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 February 28, 2023. An Agency may not conduct, or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before August 29, 2022.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OA–2019–0296, online using *www.regulations.gov* (our preferred method) or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

The 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: Candi Schaedle, NEPA Compliance Division, Office of Federal Activities, Mail Code 2501G, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202–564–6121; email address: *schaedle.candi@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 the EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, the 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. The 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, the 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 National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321–4347 establishes a national policy for the environment. The Council on Environmental Quality (CEQ) oversees the NEPA implementation. CEQ's Regulations at 40 CFR parts 1500 through 1508 set the standard for NEPA compliance. They also require agencies to establish their own NEPA implementing procedures. The EPA's procedures for implementing NEPA are found in 40 CFR part 6. Through this part, the EPA adopted the CEQ Regulations and supplemented those regulations for actions proposed by the EPA that are subject to NEPA requirements. The EPA actions subject to NEPA include the award of wastewater treatment construction grants under section 201 of the Clean Water Act, the EPA's issuance of new source National Pollutant Discharge

Elimination System (NPDES) permits under section 402 of the Clean Water Act, certain research and development projects, the EPA actions involving renovations or new construction of EPA facilities, and certain grants awarded for projects authorized by Congress through the agency's annual appropriations act. The EPA is collecting information from certain applicants as part of the process of complying with either NEPA or Executive Order 12114 (''Environmental Effects Abroad of Major Federal Actions''). The EPA's NEPA regulations apply to actions of the EPA that are subject to NEPA in order to ensure that environmental information is available to the agency's decision-makers and the public before decisions are made and before actions are taken. When the EPA conducts an environmental assessment pursuant to its Executive Order 12114 procedures, the agency generally follows its NEPA procedures. Compliance with the procedures is the responsibility of the EPA's Responsible Officials, and for applicant proposed actions, applicants may be required to provide environmental information to the EPA as part of the environmental review process. For this ICR, applicant-proposed projects subject to either NEPA or Executive Order 12114 (and that are not addressed in other EPA programs' ICRs) are addressed through the NEPA process.

Form Numbers: None.

Respondents/affected entities: Entities potentially affected by this action are certain grant or permit applicants who must submit environmental information documentation to the EPA for their projects to comply with NEPA or Executive Order 12114, including Wastewater Treatment Construction Grants Program facilities funded under section 201 of the Clean Water Act, State and Tribal Assistance Grant recipients, and new source NPDES permittees.

Respondent's obligation to respond: Voluntary.

Estimated number of respondents: 516 (total).

Frequency of response: On occasion.

Total estimated burden: 27,004 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $2,290,209 (per year), includes $0 annualized capital or operation & maintenance costs.

Changes in Estimates: There is an increase of 19,444 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This increase is due to an adjustment change in the size of the respondent universe due to the return of congressional earmarks in the EPA annual appropriations act.

Dated: June 23, 2022.

Robert Tomiak,

Director, Office of Federal Activities.

[FR Doc. 2022–13790 Filed 6–27–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2021–0119; FRL—9974–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Taconite Iron Ore Processing (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NESHAP for Taconite Iron Ore Processing (EPA ICR Number 2050.10, OMB Control Number 2060–0538), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through June 30, 2022. Public comments were previously requested, via the **Federal Register**, on April 13, 2021 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before July 28, 2022.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2021–0119, online using *www.regulations.gov* (our preferred method) or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 2821T, 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.

Submit written comments and recommendations to OMB for the proposed information collection 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: Muntasir Ali, Sector Policies and Program Division (D243–05), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–0833; email address: *ali.muntasir@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 *https://www.regulations.gov,* or in person at the EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: The National Emission Standards for Hazardous Air Pollutants (NESHAP) for Taconite Iron Ore Processing (40 CFR part 63, subpart RRRRR), were proposed on December 18, 2002; promulgated on October 30, 2003; and most-recently amended on both July 28, 2020 and November 19, 2020. These regulations apply to existing facilities and new taconite iron ore processing facilities that emit or have the potential to emit a single hazardous air pollutant (HAP) at a rate of 10 tons or more per year or any combination of HAPs at a rate of 25 tons or more per year. The affected sources are ore crushing and handling operations, ore dryers, indurating furnaces, finished pellet handling emission units, and fugitive dust emissions. New facilities include those that commenced construction or reconstruction after the date of proposal. This information is being collected to assure compliance with 40 CFR part 63, subpart RRRRR. In general, all NESHAP standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is

inoperative. These notifications, reports, and records are essential in determining compliance, and are required of all affected facilities subject to NESHAP.

Form Numbers: 5900–576.

Respondents/affected entities: Taconite iron ore processing facilities.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart RRRRR).

Estimated number of respondents: 8 (total).

Frequency of response: Initially, occasionally, and semiannually.

Total estimated burden: 1,230 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $584,000 (per year), which includes $0 in annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: There is an adjustment increase in the total estimated burden as currently identified in the OMB Inventory of Approved Burdens. This increase is not due to any program changes. The change in the burden and cost estimates is due to a correction of the number of respondents per year performing Method 5 performance tests to be consistent with the number of respondents estimated to provide notifications of performance tests and report performance test results. This ICR adjusts the number of respondents conducting performance tests in each year from 2.7 per year to 8 per year, which increases the annual burden by approximately 300 hours. There is no change in the capital/startup vs. operation and maintenance (O&M) costs as calculated in section 6(b)(iii) compared with the costs in the previous ICR.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2022–13757 Filed 6–27–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2012–0103; FRL–9975–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Diesel Emissions Reduction Act (DERA) and Clean School Bus (CSB) Rebate Programs

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Diesel Emissions Reduction Act (DERA) and Clean School Bus (CSB) Rebate Programs (EPA ICR No. 2461.04, OMB Control No. 2060–0686) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through June 30, 2022. Public comments were previously requested via the **Federal Register** on August 16, 2021 and February 2, 2022, both with 60-day comment periods. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before July 28, 2022.

ADDRESSES: Submit your comments to EPA, referencing Docket ID No. EPA–HQ–OAR–2012–0103, online using *www.regulations.gov* (our preferred method), by email to *a-and-r-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.

Submit written comments and recommendations to OMB for the proposed information collection 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: Jason Wilcox, Office of Transportation and Air Quality, (6406A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202–343–9571; fax number: 202–343–2803; email address: *wilcox.jason@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: This is an extension of the current Information Collection Request (ICR) for the Diesel Emissions Reduction Act program (DERA) authorized by Title VII, Subtitle G (Sections 791 to 797) of the Energy Policy Act of 2005 (Pub. L. 109–58), as amended by the Diesel Emissions Reduction Act of 2010 (Pub. L. 111–364) and Division S (Section 101) of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), codified at 42 U.S.C. 16131 *et seq.* DERA provides the Environmental Protection Agency (EPA) with the authority to award grants, rebates or low-cost revolving loans on a competitive basis to eligible entities to fund the costs of projects that significantly reduce diesel emissions from mobile sources through implementation of a certified engine configuration, verified technology, or emerging technology. Eligible mobile sources include buses (including school buses), medium heavy-duty or heavy heavy-duty diesel trucks, marine engines, locomotives, or nonroad engines or diesel vehicles or equipment used in construction, handling of cargo (including at ports or airports), agriculture, mining, or energy production. In addition, eligible entities may also use funds awarded for programs or projects to reduce long-duration idling using verified technology involving a vehicle or equipment described above. The objective of the assistance under this program is to achieve significant reductions in diesel emissions in terms of tons of pollution produced and reductions in diesel emissions exposure, particularly from fleets operating in areas designated by the Administrator as poor air quality areas. EPA uses approved procedures and forms to collect necessary information to operate its grant and rebate programs. EPA has been providing rebates under DERA since Fiscal Year 2012. EPA is requesting an extension of the current ICR, which is approved through June 30, 2022, for forms needed to collect necessary information to operate a rebate program as authorized by Congress under the DERA program.

As part of this extension, EPA is revising the ICR to address the needs of the Clean School Bus (CSB) Program. This program is authorized by Title XI, Section 71101 of the Infrastructure Investment and Jobs Act (Pub. L. 117–58). The new program, like DERA,

allows for rebates and grants for school bus replacement projects that reduce emissions.

EPA will collect information from applicants who wish to apply for a rebate under DERA or CSB. Information collected from applicants will ensure that they are eligible to receive funds, that funds are provided for eligible activities, and to satisfy the reporting requirements of DERA and CSB.

Form Numbers: 2060–0686.

Respondents/affected entities: Those interested in applying for a rebate under EPA's Diesel Emission Reduction Act (DERA) or Clean School Bus (CSB) Program and include but are not limited to the following NAICS (North American Industry Classification System) codes: 23 Construction; 482 Rail Transportation; 483 Water Transportation; 484 Truck Transportation; 485 Transit and Ground Passenger Transportation; 4854 School and Employee Bus Transportation; 48831 Port and Harbor Operations; 61111 Elementary and Secondary Schools; 61131 Colleges, Universities, and Professional Schools; 9211 Executive, Legislative, and Other Government Support; and 9221 Justice, Public Order, and Safety Activities.

Respondent's obligation to respond: Voluntary.

Estimated number of respondents: 3,000 (total).

Frequency of response: Voluntary as needed.

Total estimated burden: 17,287 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $732,996.58 (per year), includes $0 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is no change in the total estimated respondent burden compared with the ICR currently approved by OMB.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2022–13758 Filed 6–27–22; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0710; FR ID 93122]

Information Collection Being Submitted for Review and Approval to Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.'' The Commission 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 comments and recommendations for the proposed information collection should be submitted on or before July 28, 2022.

ADDRESSES: Comments should be sent 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. Your comment must be submitted into *www.reginfo.gov* per the above instructions for it to be considered. In addition to submitting in *www.reginfo.gov* also send a copy of your comment on the proposed information collection to Nicole Ongele, FCC, via email to *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Nicole Ongele at (202) 418–2991. To view a copy of this information collection request (ICR) submitted to OMB: (1) go to the web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (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 burden estimates; (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 the respondents, including the use of automated collection techniques or other forms of information technology. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

OMB Control Number: 3060–0710.

Title: Policy and Rules Under Parts 1 and 51 Concerning the Implementation of the Local Competition Provisions in the Telecommunications Act of 1996, CC Docket No. 96–98.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents and Responses: 15,282 respondents; 1,067,987 responses.

Estimated Time per Response: 0.50–4,000 hours.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in sections 1–4, 201–205, 214, 224, 251, 252, and 303(r) of the Communications Act of 1934, as amended, and section 601 of the Telecommunications Act of 1996. 47 U.S.C. 151–154, 201–205, 224, 251, 252, 303(r), and 601.

Frequency of Response: On occasion reporting requirement, recordkeeping requirement, and third-party disclosure requirement.

Total Annual Burden: 645,798 hours.

Total Annual Cost: No cost.

Privacy Act Impact Assessment: No impact(s).

Nature of Extent of Confidentiality: The Commission is not requesting that the respondents submit confidential information to the FCC. Respondents

may, however, request confidential treatment for information they believe to be confidential under 47 CFR Section 0.459 of the Commission's rules.

Needs and Uses: This collection will be submitted as an extension of a currently approved collection to the Office of Management and Budget (OMB) in order to obtain the full three-year clearance.

The Commission adopted rules to implement the First Report and Order on Reconsideration issued in CC Docket No. 96–98. That Order implemented parts of sections 251 and 252 of the Telecommunications Act of 1996 that affect local competition. Incumbent local exchange carriers (ILECs) are required to offer interconnection, unbundled network elements (UNEs), transport and termination, and wholesale rates for certain services to new entrants. Incumbent LECs must price such services and rates that are cost-based and just and reasonable and provide access to right-of-way as well as establish reciprocal compensation arrangements for the transport and termination of telecommunications traffic.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2022–13764 Filed 6–27–22; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1285; FR ID 92816]

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 (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. 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 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 Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before August 29, 2022. 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: 3060–1285.

Title: Compliance with the Non-IP Call Authentication Solution Rules; Robocall Mitigation Database (RMD).

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: 8,970 respondents; 8,970 responses.

Estimated Time per Response: 0.5 hours (30 minutes)–3 hours.

Frequency of Response: Recordkeeping requirement and on occasion reporting requirement.

Obligation to Respond: Mandatory and required to obtain or retain benefits. Statutory authority for these collections are contained in 47 U.S.C. 227b, 251(e), and 227(e) of the Communications Act of 1934.

Total Annual Burden: 20,503 hrs.

Total Annual Cost: No Cost.

Privacy Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: The Commission will consider the potential confidentiality of any information submitted, particularly where public release of such information could raise security concerns (*e.g.,* granular location information). Respondents may request materials or information submitted to the Commission or to the Administrator be withheld from public inspection under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: The Pallone-Thune Telephone Robocall Abuse Criminal Enforcement and Deterrence (TRACED) Act directs the Commission to require, no later than 18 months from enactment, all voice service providers to implement STIR/SHAKEN caller ID authentication technology in the internet protocol (IP) portions of their networks and implement an effective caller ID authentication framework in the non-IP portions of their networks. Among other provisions, the TRACED Act also directs the Commission to create extension mechanisms for voice service providers. On September 29, 2020, the Commission adopted its *Call Authentication Trust Anchor Second Report and Order. See Call Authentication Trust Anchor,* WC Docket No. 17–97, Second Report and Order, 36 FCC Rcd 1859 (adopted Sept. 29, 2020). The *Second Report and Order* implemented section 4(b)(1)(B) of the TRACED Act, in part, by requiring a voice service provider maintain and be ready to provide the Commission upon request with documented proof that it is participating, either on its own or through a representative, including third party representatives, as a member of a working group, industry standards group, or consortium that is working to develop a non-internet Protocol caller identification authentication solution, or actively testing such a solution. The *Second Report and Order* also implemented the extension mechanisms in section 4(b)(5) by, in part, requiring voice service providers to certify that they have either implemented STIR/SHAKEN or a robocall mitigation program in the Robocall Mitigation Database. On May 19, 2022, the Commission adopted similar obligations for gateway providers. *See Advanced Methods to Target and Eliminate Unlawful Robocalls, Call Authentication Trust Anchor,* CG Docket No. 17–59, WC Docket No. 17–97, Sixth Report and Order et al., FCC 22–37 (adopted May 19, 2022). Specifically, like voice service providers, gateway providers were required to maintain and be ready to provide the Commission upon request with documented proof that they are participating, either on their own or through a representative, including third party representatives, as a member of a working group, industry standards group, or consortium that is working to develop a non-internet

Protocol caller identification authentication solution, or actively testing such a solution. Gateway providers were also required to implement both STIR/SHAKEN on the IP portions of their networks as well as a robocall mitigation program. They must also certify to their implementation and file a robocall mitigation plan in the Robocall Mitigation Database.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2022–13763 Filed 6–27–22; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0360; FR ID 93181]

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 collection. 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 August 29, 2022. 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 Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–0360.

Title: Section 80.409, Station Logs (Maritime Services).

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, not-for-profit institutions, and state, local and tribal government.

Number of Respondents: 19,919 respondents; 19,919 responses.

Estimated Time per Response: 27.3–95 hours.

Frequency of Response: Recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in 47 U.S.C. 151–155, 301–609.

Total Annual Burden: 559,901 hours.

Annual Cost Burden: No cost.

Needs and Uses: The Commission will submit this extension (no change in the recordkeeping requirement) to the OMB after this 60 day comment period to obtain the full three-year clearance from them. The information collection requirements are as follows:

Section 80.409(c), Public Coast Station Logs: This requirement is necessary to document the operation and public correspondence of public coast radio telegraph, public coast radiotelephone stations, and Alaska public-fixed stations, including the logging of distress and safety calls where applicable. Entries must be made giving details of all work performed which may affect the proper operation of the station. Logs must be retained by the licensee for a period of two years from the date of entry, and, where applicable, for such additional periods such as logs relating to a distress situation or disaster must be retained for three years from the date of entry in the log. If the Commission has notified the licensee of an investigation, the related logs must be retained until the licensee is specifically authorized in writing to destroy them. Logs relating to any claim or complaint of which the station licensee has notice must be retained until the claim or complaint has been satisfied or barred by statute limiting the time for filing suits upon such claims.

Section 80.409(d), Ship Radiotelegraph Logs: Logs of ship stations which are compulsorily equipped for radiotelegraphy and operating in the band 90 to 535 kHz must contain specific information in log entries according to this subsection.

Section 80.409(e), Ship Radiotelephone Logs: Logs of ship stations which are compulsorily equipped for radiotelephony must contain specific information in applicable log entries and the time of their occurrence.

The recordkeeping requirements contained in section 80.409 is necessary to document the operation and public correspondence service of public coast radiotelegraph, public coast radiotelephone stations and Alaska-public fixed stations, ship radiotelegraph, ship radiotelephone and applicable radiotelephone including the logging of distress and safety calls where applicable.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2022–13760 Filed 6–27–22; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0653; FR ID 93168]

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 collection. 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 August 29, 2022. 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 Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0653.

Title: Sections 64.703(b) and (c), Consumer Information—Posting by Aggregators.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 56,075 respondents; 5,339,038 responses.

Estimated Time per Response: .017 hours (1 minute) to 3 hours.

Frequency of Response: On occasion reporting requirements; Third party disclosure.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this information collection is found at section 226 [47 U.S.C. 226] Telephone Operator Services codified at 47 CFR 64.703(b) Consumer Information.

Total Annual Burden: 174,401 hours.

Total Annual Cost: $1,558,212.

Needs and Uses: The information collection requirements included under this OMB Control Number 3060–0653, requires aggregators (providers of telephones to the public or to transient users of their premises) under 47 U.S.C. 226(c)(1)(A), 47 CFR 64.703(b) of the Commission's rules, to post in writing, on or near such phones, information about the pre-subscribed operator services, rates, carrier access, and the FCC address to which consumers may direct complaints.

Section 64.703(c) of the Commission's rules requires the posted consumer information to be added when an aggregator has changed the pre-subscribed operator service provider (OSP) no later than 30 days following such change. Consumers will use this information to determine whether they wish to use the services of the identified OSP.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2022–13754 Filed 6–27–22; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[ET Docket No. 19–138; DA 22–611; FRS 92669]

The Federal Communications Commission: Seeks Comment on a Request for Nationwide Waiver of Intelligent Transportation System Rules To Use C–V2X Technology in the 5.895–5.925 GHz Band

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: The Federal Communications Commission's Wireless Telecommunications Bureau (WTB) and Public Safety and Homeland Security Bureau (PSHSB) issue this *Public Notice* seeking comment on a joint filing by certain automakers, state departments of transportation, and equipment manufacturers requesting a waiver of the Commission's rules governing intelligent transportation system (ITS) operations to permit them to deploy Cellular Vehicle-to-Everything (C–V2X) technology immediately in the upper 30 megahertz (5.895–5.925 GHz) portion of the 5.850–5.925 GHz Band (5.9 GHz Band). Importantly, the waiver seeks authority to deploy C–V2X technology before the Commission renders its final decision on the rules for the technical and logistical parameters of C–V2X that will ultimately govern ITS operations in the band. The *Public Notice* provides specific information about the waiver request as well as instructions on how to submit comments in the docket and the schedule for doing so.

ADDRESSES: Federal Communications Commission, 45 L Street NE, Washington, DC 20554.

DATES: Issued on June 28, 2022. Comments are due July 28, 2022. Reply Comments are due August 29, 2022.

FOR FURTHER INFORMATION CONTACT: Thomas Reed, Attorney Advisor, Mobility Division, Wireless Telecommunications Bureau, at *Thomas.Reed@fcc.gov* or (202) 418–0531, or Roberto Mussenden, Senior Attorney, Policy and Licensing Division, Public Safety and Homeland Security Bureau, at *Roberto.Mussenden@fcc.gov* or (202) 418–1428.

SUPPLEMENTARY INFORMATION: This is a summary of a public notice seeking comment on a request for waiver of the Federal Communication Commission's rules governing intelligent transportation service operations in the 5.895–5.925 GHz Band, ET Docket No. 19–138, DA 22–611, on June 7, 2022. The full text of this document is available for public inspection at the following internet address: *https://www.fcc.gov/document/wtb-pshsb-seek-comment-its-rule-waiver-use-c-v2x-59ghz-band.* Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format), by sending an email to *FCC504@fcc.gov* or calling the Consumer and Governmental Affairs Bureau at 202–418–0530 (voice) or 202–418–0432 (TTY).

Synopsis: By this *Public Notice* (PN), the Wireless Telecommunications Bureau and the Public Safety and Homeland Security Bureau (the Bureaus) seek comment on a joint filing by certain automakers, state departments of transportation (DOTs), and equipment manufacturers (collectively, the C–V2X Joint Waiver Parties),[1] requesting a waiver of the Commission's rules applicable to intelligent transportation system (ITS) operations in the upper 30 megahertz (5.895–5.925 GHz) portion of the 5.850–5.925 GHz Band (5.9 GHz Band) ''to permit them to collectively deploy and facilitate deployment of Cellular Vehicle-to-Everything ('C–V2X') technology immediately.'' [2] Specifically,

[1] This waiver request was submitted by Audi of America, Inc., Ford Motor Company, Jaguar Land Rover, the Utah Department of Transportation, the Virginia Department of Transportation, AAEON Technology Inc., Advantech Co., Ltd., Applied Information, Inc., Cohda Wireless Pty Ltd., Commsignia, Inc., Danlaw Inc., HARMAN International Industries, Inc., Kapsch TrafficCom USA Inc., and Panasonic Corporation of North America.

[2] *See* Request for Waiver of 5.9 GHz Band Rules to Permit Initial Deployments of Cellular Vehicle-to-Everything Technology, Ford Motor Company, et al., ET Docket No. 19–138, at 1 (filed Dec. 13, 2021) (*C–V2X Joint Waiver Request*): *https://www.fcc.gov/ecfs/file/download/DOC-5f6d7d2ef3400000-*

Continued

the C–V2X Joint Waiver Parties seek a waiver of 47 CFR 2.106, NG160 [3] to allow nationwide use of the upper 30 megahertz of the 5.9 GHz Band for C–V2X operating in the Intelligent Transportation System (ITS), conditioned on the technical parameters set forth in Appendix 1 of their submission.[4] They also seek a waiver of certain part 90 and part 95 rules (47 CFR 90.375, 90.377, 90.379, 95.3159, 95.3163, 95.3167, and 95.3189) [5] governing the operation of roadside units (RSUs) and on-board units (OBUs) in the upper 30 megahertz of the 5.9 GHz Band.[6]

In its *5.9 GHz First Report and Order and Further Notice,* adopted on November 20, 2020, the Commission retained the upper 30 megahertz of the 5.9 GHz Band for ITS operations, and it required that, following a transition period, ITS operations transition from Dedicated Short-Range Communication (DSRC) technology to C–V2X technology rules. In the Further Notice portion of its decision, the Commission sought comment on the rules for the technical and logistical parameters of C–V2X that ultimately would govern ITS operations in the band.[7] While part 90 ITS licensees operating in the upper 30 megahertz are authorized to operate ITS under DSRC-based rules pending adoption of final C–V2X rules, the Commission also recognized that licensees may wish to operate C–V2X-based ITS prior to adoption of those final rules.[8] Accordingly, the Commission directed the Bureaus to issue a public notice providing guidance for licensees that may wish to obtain waivers of the existing DSRC-based rules to operate C–V2X operations, either through a streamlined waiver request process (if requesters qualify), or through our normal section 1.925 waiver process.[9]

Guidance PN. The *Guidance PN,* issued on August 6, 2021, provided the following guidance to waiver applicants who elect to use the normal section 1.925 process:

> If an ITS waiver applicant that seeks authority to operate C–V2X-based roadside units or on-board units in the 5.895–5.925 GHz band is unable to comply with the existing ITS technical rules found in 47 CFR 90.371–90.383 or 47 CFR 95.3167–95.3189, respectively, they should include in their general waiver request the certifications from the streamlined waiver process outlined in this PN that they are unable to meet, the specific existing rules that they are unable to comply with, along with a specific proposal of the technical specifications they seek to use instead, and an explanation of why a waiver is warranted under Section 1.925. To facilitate granting of qualifying waiver requests, and in light of the alternate technical specifications proposed in their waiver, we would generally expect the ITS waiver applicant to include a demonstration showing that their requested waiver would not cause a greater potential for interference to other users operating in the 5.895–5.925 GHz band than DSRC-based operations in this band, and otherwise to address how the public interest would be served by such a waiver under Section 1.925. Based on the proposed change in technical parameters, the waiver request should also address any conditions (*e.g.,* coordination zone radius, per 47 CFR 90.371(b)) necessary to protect Federal Government Relocation Services.[10]

C–V2X Joint Waiver Request. In the *C–V2X Joint Waiver Request,* the automakers (Audi, Ford, and Jaguar Land Rover) seek a waiver in order to introduce C–V2X into their vehicle fleets throughout the United States as soon as possible.[11] As noted in their request, the C–V2X Joint Waiver Parties further seek permission for nationwide C–V2X OBU operations.[12] Specifically, they ask that the Commission waive its rules to the extent necessary to allow the Utah and Virginia DOTs to deploy C–V2X RSUs throughout their respective states, both RSUs and OBUs, under the FCC ITS licenses each currently holds,[13] and allow each of the identified automakers to deploy C–V2X-based OBUs in all of its cars sold in the United States.[14] The C–V2X Joint Waiver Parties also request that the Commission waive its rules to the extent necessary to allow the identified equipment manufacturers to obtain the necessary equipment certifications for their C–V2X equipment.[15] The C–V2X Joint Waiver Parties state that while the automakers and state departments of transportation will initially deploy C–V2X technology based on LTE technology (3GPP Releases 14 and 15), the parties request the flexibility to deploy 5G-based C–V2X (3GPP Release 16), as well.[16] If granted, the net effect of the waiver would be to allow C–V2X operations in Utah and Virginia and the equipping of vehicles nationwide with C–V2X OBUs.

In their request, the C–V2X Joint Waiver Parties ask the Commission to permit C–V2X-based operations on 20 megahertz (5905–5925 MHz) in the ITS band, pending adoption of final C–V2X-based rules, which meet the technical parameters set forth in the tables below.[17]

A.pdf?file_name=C-V2X%20Waiver%20Request%2012%2013%202021.pdf. More recently, additional information on the request was submitted to the Commission. *See* Letter from the C–V2X Joint Waiver Parties to Marlene H. Dortch, Secretary, FCC, ET Docket No. 19–138 (filed Apr. 20, 2022) (*C–V2X Joint Waiver Request Supplement*): *https://www.fcc.gov/ecfs/search/search-filings/results?q=(proceedings.name:(%2219-138%22)+AND+date_received:(2021-12-01%20TO%202022-05-23)).*

[3] ''In the band 5895–5925 MHz, the use of the non-federal mobile service is limited to operations in the Intelligent Transportation Systems radio service.'' 47 CFR 2.106, NG160.

[4] *C–V2X Joint Waiver Request* at 2; *see also C–V2X Joint Waiver Request Supplement* at 3–4.

[5] *See* 47 CFR 90.375, 90.377, 90.379, 95.3159, 95.3163, 95.3167, and 95.3189.

[6] *See C–V2X Joint Waiver Request* at 2.

[7] *Use of the 5.850–5.925 GHz Band,* ET Docket No. 19–138, First Report and Order, Further Notice of Proposed Rulemaking, and Order of Proposed Modification, 35 FCC Rcd 13440, 13464–65, para. 55 (2020) (*5.9 GHz First Report and Order and Further Notice*). The Commission has not yet rendered a decision on the rule changes proposed in the Further Notice of Proposed Rulemaking.

[8] *5.9 GHz First Report and Order,* 35 FCC Rcd at 13464, para. 55.

[9] *See Wireless Telecommunications Bureau and Public Safety and Homeland Security Bureau Provide Guidance for Waiver Process to Permit Intelligent Transportation System Licensees to Use C–V2X Technology in the 5.895–5.925 GHz Band,* Public Notice, DA 21–962 (WTB, PSHSB Aug. 6, 2021), at 2 (*Guidance PN*).

[10] *Guidance PN* at 2–3, n.10.

[11] *C–V2X Joint Waiver Request* at 3–4.

[12] *C–V2X Joint Waiver Request Supplement* at 4.

[13] *C–V2X Joint Waiver Request* at 4–5. Utah DOT holds FCC license WQCE200. Virginia DOT holds FCC license WQCU200.

[14] *C–V2X Joint Waiver Request* at 4–5.

[15] *Id.* at 5.

[16] *C–V2X Joint Waiver Request Supplement* at 4, notes 15, 16.

[17] *C–V2X Joint Waiver Request* Appendix 1 at 10–11; *C–V2X Joint Waiver Request Supplement* at 3. The *C–V2X Joint Waiver Request Supplement* did not change the technical parameters proposed in the *C–V2X Joint Waiver Request.*

C–V2X OBU AND RSU OPERATIONS UNDER C–V2X JOINT WAIVER REQUEST

Frequency range	Channel bandwidth	OBU transmitter output power/EIRP * limits	RSU EIRP limit	RSU antenna center line height above roadway bed surface
5905–5925 MHz	20 MHz	20 dBm/33 dBm	33 dBm	For heights of 8 meters or less. Or in the alternative, the RSU EIRP is reduced by a factor of 20 × log(height/8) for heights 15 meters or less (but greater than 8 meters).

* EIRP (equivalent isotropically radiated power).

C–V2X JOINT WAIVER REQUEST OUT-OF-BAND EMISSIONS (OOBE) LIMITS

Frequency offset (MHz from channel edge)	OOBE power spectral density offset relative to 33 dBm/20 MHz (or 10 dBm/100 MHz)	OOBE power spectral density for C–V2X transmissions (dBm/100 kHz)
0.0	−26.0	−16.0
1.0	−32.0	−22.0
10.0	−40.0	−30.0
20.0	−50.0	−40.0

In their filings, the C–V2X Joint Waiver Parties provide additional discussion and explanation, asserting that the public interest would be served if the Commission were to permit C–V2X operations pending adoption of final C–V2X-based rules, and that these materials provide sufficient support for the Commission to grant waiver(s) of its rules to the extent necessary to permit the proposed C–V2X operations.[18] They contend that their proposed technical parameters for C–V2X operations are generally consistent with DSRC parameters and unlikely to raise interference concerns to existing licensed services in the band.[19] They also agree, as a condition of any waiver grant, they would be obligated to comply with any final rules that the Commission adopts for C–V2X operations.[20]

Public Comment on Waiver. Prior to evaluating the merits of the *Joint C–V2X Waiver Request,* and in order to assist in assessing the request, the Bureaus seek comment on this waiver request, including whether the request contains sufficient information for the Commission to grant their request or whether additional modifications or clarifications would be appropriate.

Procedural Matters

To develop a complete record on the issues presented by this request, the proceeding will be treated, for *ex parte* purposes, as a ''permit-but-disclose'' proceeding in accordance with Section 1.1200(a) of the Commission's rules, subject to the requirements under Section 1.1206(b). Parties should file all comments and reply comments in ET Docket No. 19–138.

Filing Requirements. Parties may file comments, identified by ET Docket No. 19–138, by any of the following methods:

- *Electronic Filers:* Comments may be filed electronically using the internet by accessing the ECFS: *https://www.fcc.gov/ecfs/.*
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing.

Filings can be sent by commercial courier or by the U.S. Postal Service. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- Commercial deliveries (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.
- U.S. Postal Service First-Class, Express, and Priority mail must be addressed to 45 L Street NE, Washington, DC 20554.
- Effective March 19, 2020, and until further notice, the Commission no longer accepts any hand or messenger delivered filings. This is a temporary measure taken to help protect the health and safety of individuals, and to mitigate the transmission of COVID–19. See FCC Announces Closure of FCC Headquarters Open Window and Change in Hand-Delivery Policy, Public Notice, DA 20–304 (March 19, 2020). *https://www.fcc.gov/document/fcc-closes-headquarters-open-window-and-changeshanddelivery-policy.*
- During the time the Commission's building is closed to the general public and until further notice, if more than one docket or rulemaking number appears in the caption of a proceeding, paper filers need not submit two additional copies for each additional docket or rulemaking number; an original and one copy are sufficient.

People with Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Government Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

By the Acting Chief, Wireless Telecommunications Bureau, and the Chief, Public Safety and Homeland Security Bureau.

Amy Brett,

Acting Chief of Staff, Wireless Telecommunications Bureau.

[FR Doc. 2022–13793 Filed 6–27–22; 8:45 am]

BILLING CODE 6712–01–P

[18] *See generally C–V2X Joint Waiver Request; C–V2X Joint Waiver Request Supplement.*

[19] *See, e.g., C–V2X Joint Waiver Request Supplemental* at 4.

[20] *Id.* at 4.

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 87 FR 36325.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING:

Thursday, June 23, 2022 at 10:00 a.m.

Hybrid Meeting: 1050 First Street NE, Washington, DC (12th Floor) and virtual.

CHANGES IN THE MEETING:

The following matter was also considered:

Draft Advisory Opinion 2022–08: National Republican Congressional Committee (''NRCC'').

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Authority: Government in the Sunshine Act, 5 U.S.C. 552b.

Vicktoria J. Allen,

Acting Deputy Secretary of the Commission.

[FR Doc. 2022–13823 Filed 6–24–22; 11:15 am]

BILLING CODE 6715–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0129; Docket No. 2022–0053; Sequence No. 12]

Submission for OMB Review; Cost Accounting Standards Administration

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division has submitted to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement regarding cost accounting standards administration.

DATES: Submit comments on or before July 28, 2022.

ADDRESSES: Written comments and recommendations for this information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

Additionally, submit a copy to GSA through *https://www.regulations.gov* and follow the instructions on the site. This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments.

Instructions: All items submitted must cite OMB Control No. 9000–0129, Cost Accounting Standards Administration. Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two-to-three days after submission to verify posting. If there are difficulties submitting comments, contact the GSA Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov*.

FOR FURTHER INFORMATION CONTACT: Zenaida Delgado, Procurement Analyst, at telephone 202–969–7207, or *zenaida.delgado@gsa.gov*.

SUPPLEMENTARY INFORMATION:

A. OMB Control Number, Title, and Any Associated Form(s)

9000–0129, Cost Accounting Standards Administration.

B. Need and Uses

This justification supports an extension of the expiration date of OMB Control No. 9000–0129. This clearance covers the information that contractors must submit to comply with the Federal Acquisition Regulation (FAR) clause at 52.230–6, Administration of Cost Accounting Standards. This FAR clause requires contractors performing Cost Accounting Standards (CAS) covered contracts to submit notifications and descriptions of certain cost accounting practice changes, including revisions to their Disclosure Statements, if applicable. Often these descriptions are quite complex.

This information is used by contracting officers for ascertaining compliance with CAS.

C. Annual Burden

Respondents: 607.
Total Annual Responses: 1,821.
Total Burden Hours: 318,675.

D. Public Comment

A 60-day notice was published in the **Federal Register** at 87 FR 23862, on April 21, 2022. No comments were received.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202–501–4755 or emailing *GSARegSec@gsa.gov*. Please cite OMB Control No. 9000–0129, Cost Accounting Standards Administration.

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2022–13784 Filed 6–27–22; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0026; Docket No. 2022–0053; Sequence No. 13]

Submission for OMB Review; Change Order Accounting and Notification of Changes

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division has submitted to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement regarding change order accounting and notification of changes.

DATES: Submit comments on or before July 28, 2022.

ADDRESSES: Written comments and recommendations for this information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

Additionally, submit a copy to GSA through *https://www.regulations.gov* and follow the instructions on the site. This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments.

Instructions: All items submitted must cite OMB Control No. 9000–0026, Change Order Accounting and Notification of Changes. Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two-to-three days after submission to verify posting. If there are difficulties submitting comments, contact the GSA Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov*.

FOR FURTHER INFORMATION CONTACT: Zenaida Delgado, Procurement Analyst, at telephone 202–969–7207, or *zenaida.delgado@gsa.gov*.

SUPPLEMENTARY INFORMATION:

A. OMB Control Number, Title, and Any Associated Form(s)

9000–0026, Change Order Accounting and Notification of Changes.

B. Need and Uses

This justification supports extension of the expiration date of OMB Control No. 9000–0026. This clearance covers the information that contractors must submit to comply with the Federal Acquisition Regulation (FAR) part 43

requirements as stated in the following clauses:

a. 52.243–4, Changes. For acquisitions for dismantling, demolition, or removal of improvements; and fixed-price construction contracts that exceed the simplified acquisition threshold (SAT), the contractor must assert its right to an adjustment under this clause within 30 days after receipt of a written change order or the furnishing of a written notice, by submitting to the contracting officer a written statement describing the general nature and amount of proposal, unless this period is extended by the Government. The written notice covers any other written or oral order (which includes direction, instruction, interpretation, or determination) from the contracting officer that causes a change. The contractor gives the contracting officer written notice stating (1) the date, circumstances, and source of the order and (2) that the contractor regards the order as a change order. The statement of proposal for adjustment may be included in the written notice.

b. 52.243–6, Change Order Accounting. The contracting officer may require change order accounting whenever the estimated cost of a change or series of related changes exceeds $100,000. The contractor, for each change or series of related changes, shall maintain separate accounts, by job order or other suitable accounting procedure, of all incurred segregable, direct costs (less allocable credits) of work, both changed and not changed, allocable to the change. The contractor shall maintain these accounts until the parties agree to an equitable adjustment or the matter is conclusively disposed of under the Disputes clause. This requirement is necessary in order to be able to account properly for costs associated with changes in supply and research and development (R&D) contracts of significant technical complexity, if numerous changes are anticipated, or construction contracts if deemed appropriate by the contracting officer.

c. 52.243–7, Notification of Changes. The clause is available for use primarily in negotiated R&D or supply contracts for the acquisition of major weapon systems or principal subsystems. If the contract amount is expected to be less than $1,000,000, the clause shall not be used, unless the contracting officer anticipates that situations will arise that may result in a contractor alleging that the Government has effected changes other than those identified as such in writing and signed by the contracting officer. The contractor shall notify the Administrative Contracting Officer in writing if the contractor identifies any Government conduct (including actions, inactions, and written or oral communications) that the contractor regards as a change to the contract terms and conditions. This excludes changes identified as such in writing and signed by the contracting officer. On the basis of the most accurate information available to the contractor, the notice shall state—

(1) The date, nature, and circumstances of the conduct regarded as a change;

(2) The name, function, and activity of each Government individual and Contractor official or employee involved in or knowledgeable about such conduct;

(3) The identification of any documents and the substance of any oral communication involved in such conduct;

(4) In the instance of alleged acceleration of scheduled performance or delivery, the basis upon which it arose;

(5) The particular elements of contract performance for which the Contractor may seek an equitable adjustment under this clause, including—

(i) What line items have been or may be affected by the alleged change;

(ii) What labor or materials or both have been or may be added, deleted, or wasted by the alleged change;

(iii) To the extent practicable, what delay and disruption in the manner and sequence of performance and effect on continued performance have been or may be caused by the alleged change;

(iv) What adjustments to contract price, delivery schedule, and other provisions affected by the alleged change are estimated; and

(6) The Contractor's estimate of the time by which the Government must respond to the Contractor's notice to minimize cost, delay or disruption of performance.

Contracting officers use the notices and information provided by contractors in response to a change notice to negotiate an equitable adjustment under the contract that may result from the change order.

C. Annual Burden

Respondents & Recordkeepers: 2,611.
Total Annual Responses: 1,152.
Total Burden Hours: 9,238 (1,152 reporting hours + 8,086 recordkeeping hours).

D. Public Comment

A 60-day notice was published in the **Federal Register** at 87 FR 24163, on April 22, 2022. No comments were received.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202–501–4755 or emailing *GSARegSec@gsa.gov*. Please cite OMB Control No. 9000–0026, Change Order Accounting and Notification of Changes.

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2022–13783 Filed 6–27–22; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Breast Cancer in Young Women; Notice of Charter Renewal

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of charter renewal.

SUMMARY: This gives notice under the Federal Advisory Committee Act of October 6, 1972, that the Advisory Committee on Breast Cancer in Young Women (ACBCYW), Centers for Disease Control and Prevention, Department of Health and Human Services, has been renewed for a 2-year period through June 17, 2024.

FOR FURTHER INFORMATION CONTACT: Kimberly E. Smith, MBA, MHA, Designated Federal Officer, National Center for Chronic Disease Prevention and Health Promotion, CDC, 4770 Buford Highway NE, Mailstop S107–4, Atlanta, Georgia 30341–3717; Telephone: (404) 498–0073; Email: *KESmith@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–13686 Filed 6–27–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number CDC–2022–0078, NIOSH–345–A]

Draft—American Indian and Alaska Native Worker Safety and Health Strategic Plan

AGENCY: The Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for information and comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) in the Centers for Disease Control and Prevention (CDC), an Operating Division of the Department of Health and Human Services (HHS), announces the availability of a draft strategic plan for public comment entitled *Revised Draft of American Indian and Alaska Native Worker Safety and Health Strategic Plan (Revised Draft Strategic Plan).*

DATES: Electronic or written comments must be received by August 29, 2022.

ADDRESSES: You may submit comments, identified by CDC–2022–0078 and docket number NIOSH–345–A, by either of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C–34, Cincinnati, Ohio 45226–1998.

Instructions: All information received in response to this notice must include the agency name and docket number [CDC–2022–0078; NIOSH–345–A]. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. Do not submit comments by email. CDC does not accept comments by email. For access to the docket to read background documents or comments received, go to *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Elizabeth Dalsey, NIOSH Western States Division, P.O. Box 25226, Denver, Colorado 80225–0226; Telephone: (303)236–5955; Email: *edalsey@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Background: On November 30, 2021, the National Institute for Occupational Safety and Health (NIOSH), within the Centers for Disease Control and Prevention (CDC), published a notice of meeting and request for testimony in the **Federal Register** [**Federal Register** Number 2021–26016] [86 FR 67949]. The **Federal Register** notice announced a CDC Tribal Consultation Session that was held on February 3, 2022. CDC/NIOSH hosted American Indian and Alaska Native (AI/AN) federally recognized tribes for a virtual tribal consultation session on the NIOSH draft strategic plan entitled *American Indian and Alaska Native Worker Safety and Health Strategic Plan.* NIOSH accepted written tribal testimony until February 24, 2022. The consultation session was held in accordance with Presidential Executive Order No. 13175, November 6, 2000, and the Presidential Memorandum of November 5, 2009, and September 23, 2004, Consultation and Coordination with Indian Tribal Government, and CDC/ATSDR's Tribal Consultation Policy which can be found at *https://www.cdc.gov/tribal/documents/consultation/policy475.pdf.* NIOSH carefully considered the oral comments from the Tribal Consultation Session and the written comments submitted to the Tribal Consultation Session docket, *https://www.cdc.gov/niosh/docket/archive/docket345/default.html.* Based on the pertinent comments received, NIOSH has developed the Revised Draft Strategic Plan on which public comment is now being requested.

NIOSH guided the development of this strategic plan and hopes the strategic plan will serve as a blueprint to enhance the health, safety, and well-being of AI/AN workers across the United States. NIOSH, tribes, tribal-serving organizations, and other interested partners can work collaboratively to accomplish the objectives outlined in the strategic plan.

AI/AN workers account for 2.7 million or 1.8% of the total U.S. workforce.[1] These workers are employed in a wide variety of occupations, with the highest numbers in office and administrative support, sales and related occupations, management, transportation, and material moving, and food preparation and serving. Many AI/AN workers are also employed through tribal enterprises such as medical care, housing, manufactured products, food production, livestock, and tourism. Tribes are often the largest employer on tribal lands.

National data on occupational injuries, illnesses, and fatalities among AI/AN workers are scarce, and there is limited research on worker safety, health, and well-being in tribal communities. Given the lack of data, the true numbers are likely much higher.

NIOSH requests input on this strategic plan for research and outreach to enhance worker safety and health in tribal communities.

Information Needs: Additional data and information are needed to ensure the Revised Draft Strategic Plan addresses research and outreach that is most critical for understanding and reducing work-related injuries, illnesses, and fatalities among AI/AN workers. NIOSH seeks comments on the following:

1. Does the Revised Draft Strategic Plan address the most pressing occupational safety and health concerns for the AI/AN workforce? If not, what would you suggest be included or removed, and why? Please provide details on other health concerns considered pressing (*e.g.,* type, prevalence, economic burden), including the reasoning for the suggestion that the health and safety concern be included or excluded from the Revised Draft Strategic Plan.

2. What recommendations do you have for NIOSH for partnering with tribal nations to conduct the activities described in this plan? Please explain the basis for your suggestion(s), such as past experiences, subject matter expertise, or collaborations on other efforts.

3. What other organizations may have an interest in collaborating with NIOSH to improve occupational safety and health for AI/AN workers? Please explain the basis of your suggestion(s) such as past experiences, subject matter expertise, or a shared mission or vision.

4. How might NIOSH improve communication with tribal nations regarding worker safety and health issues? Please include examples of the type of communication material and channel.

5. What support may be needed to address occupational safety and health concerns for the AI/AN workforce? Please provide details explaining how

the support will benefit the AI/AN workforce.

John J. Howard,

Director, National Institute for Occupational Safety and Health Centers for Disease Control and Prevention.

[FR Doc. 2022–13723 Filed 6–27–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–CE–22–013: Rigorous Evaluation of Community-Centered Approaches for the Prevention of Community Violence; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–CE–22–013: Rigorous Evaluation of Community-Centered Approaches for the Prevention of Community Violence; June 28–29, 2022, 8:30 a.m.–5:30 p.m., EDT, Videoconference.

The meeting was published in the **Federal Register** on February 4, 2022, Volume 87, Number 24, page 6551.

The meeting is being amended to change the meeting date and should read as follows:

RFA–CE–22–013: Rigorous Evaluation of Community-Centered Approaches for the Prevention of Community Violence, June 28, 2022.

The meeting is closed to the public.

FOR FURTHER INFORMATION CONTACT: Mikel Walters, Ph.D., Scientific Review Officer, National Center for Injury Prevention and Control, CDC, 4770 Buford Highway NE, Mailstop F–63, Atlanta, Georgia 30341; Telephone: (404) 639–0913; Email: *MWalters@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–13685 Filed 6–27–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health (NIOSH), Safety and Occupational Health Study Section (SOHSS); Notice of Charter Renewal

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of charter renewal.

SUMMARY: This gives notice under the Federal Advisory Committee Act of October 6, 1972, that the Safety and Occupational Health Study Section, Centers for Disease Control and Prevention, Department of Health and Human Services, has been renewed for a 2-year period through June 30, 2024.

FOR FURTHER INFORMATION CONTACT: Joanne Fairbanks, Designated Federal Officer, Safety and Occupational Health Study Section, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1095 Willowdale Road, Mailstop L1119, Morgantown, West Virginia 26505; Telephone: (304) 285–6143; Email: *JFairbanks@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–13687 Filed 6–27–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–22–1274]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Million Hearts Hospitals & Health Systems Recognition Program'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on September 17, 2021 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. 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. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Million Hearts Hospitals & Health Systems Recognition Program (OMB Control No. 0920–1274, Exp. 11/30/2022)—Revision—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Heart disease, stroke and other cardiovascular diseases (CVDs) kill over 800,000 Americans each year, accounting for one in every three deaths. CVD is the nation's number one killer among both men and women and the leading cause of health disparities. Million Hearts®, a national, public-private initiative co-led by the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS), was established to address this issue. Whether migrating towards value-based reimbursement or simply striving for a significant impact in reducing the devastation of heart attacks and strokes, clinical organizations are positioned to improve the health of the population they serve by implementing high-impact, evidence-based strategies. Achieving a Million Hearts® Hospitals & Health Systems designation signals a commitment to not only clinical quality, but population health overall.

Initially launched in 2020, the Program will continue to recognize institutions that are working to systematically improve the cardiovascular health of the population and communities that they serve by implementing strategies under the new Million Hearts® priority areas of Building Healthy Communities, Optimizing Care, Focusing on Health Equity, and Supplemental Programs and Innovations. CDC anticipates that new applicants will range from health systems with multiple hospitals, hospitals with and without ambulatory medical practices, and medical practices not affiliated with hospitals.

Any clinical entity whose leaders consider it eligible may apply. Recognition can be achieved by a robust commitment to implement specific strategies, by implementing these specific strategies, and most importantly, by achieving specific outcomes. Applicants will complete the Million Hearts® Hospitals & Health Systems Recognition Program application, indicating the areas in which they are committing to implement Million Hearts® strategies; areas in which they have implemented key strategies; and those strategies for which they have achieved outcomes/results.

Applicants must address a minimum of one strategy in at least three of the four priority areas (Building Healthy Communities, Optimizing Care, Focusing on Health Equity, and Supplemental Programs and Innovations) that are outlined in the application. However, they are encouraged to target as many strategies as is appropriate for their institution. Applicants will be subject to a background check.

All applicants with reported outcomes and a select number of those who are committing to implement or are implementing Million Hearts® strategies, will be asked to participate in a semi-structured, qualitative interview. The purpose of the interview is to obtain in-depth contextual information about the Million Hearts® strategies and facilitators used to achieve improved cardiovascular outcomes among the applicant's patient population. Applicants with reported outcomes will receive increased recognition from Million Hearts® by having their success stories highlighted by Million Hearts® by placement on the Million Hearts® website, e-newsletter, etc.

The program's web-based application will stay open throughout the year and applications will be reviewed on a quarterly basis and recognized within six months of acceptable review. CDC estimates that information will be collected from up to 50 applicants per year. CDC will use the information collected through the Million Hearts® Hospitals & Health Systems Recognition Program to increase widespread attention on successful and sustainable implementation strategies, improve understanding of these strategies at the practice level, bring visibility to organizations that commit, implement, or have implemented Million Hearts® strategies and motivate other hospitals and health systems to strengthen their efforts to address CVD.

CDC requests OMB approval for an estimated 149 annual burden hours. Participation is voluntarily and there are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Medical & Health Service Manager	Recognition Program Application	50	1	2, 40/60
Medical & Health Service Manager	Interview Guide	30	1	30/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–13742 Filed 6–27–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers CMS–10680, CMS–10692 and CMS–10788]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by July 28, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Title of Information Collection:* Electronic Visit Verification Compliance Survey; *Type of Information Collection Request:* Extension without change of a currently approved collection; *Use:* The web-based survey will allow states to self-report their progress in implementing electronic visit verification (EVV) for personal care services (PCS) and home health care services (HHCS), as required by section 1903(l) of the Social Security Act. CMS will use the survey data to assess states' compliance with section 1903(l) of the Act and levy Federal Medical Assistance Percentage (FMAP) reductions where necessary as required by 1903(l) of the Act.

The survey will be disseminated to all 51 state Medicaid agencies (including the District of Columbia) and the Medicaid agencies of five U.S. territories. States will be required to complete the survey in order to demonstrate that they are complaint with Section 1903(l) of the Act by reporting on their EVV implementation status for PCS provided under sections 1905(a)(24), 1915(c), 1915(i), 1915(j), 1915(k), and Section 1115 of the Act; and HHCS provided under 1905(a)(7) of the Act or under a demonstration project or waiver (*e.g.,* 1915(c) or 1115 of the Act).

The survey will be a live form, meaning states will have the ability to update their 1903(l) compliance status on a continuous basis. As FMAP reductions are assigned quarterly per 1903(l) of the Act, states who are not in compliance will be asked to review their survey information on a quarterly basis to ensure it is up-to-date and to update their survey responses as needed until they come into compliance. *Form Number:* CMS–10680 (OMB control number: 0938–1360); *Frequency:* On occasion; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Number of Responses:* 336; *Total Annual Hours:* 504. (For questions regarding this collection contact Ryan Shannahan at 410–786–0295.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Home and Community Based Services (HCBS) Incident Management Survey; *Use:* The Survey will be disseminated to all 51 state Medicaid agencies (including the District of Columbia) to assess incident management systems in 1915(c) waivers. States will be surveyed to identify methods and promising practices for identifying, reporting, tracking, and resolving incidents of abuse, neglect, and exploitation. The survey results will also be used to review the strengths and weaknesses of each state's incident management system and will inform guidance to help ensure compliance with sections 1902(a)(30(A) and 1915(c)(2)(A) of the Social Security Act. *Form Number:* CMS–10692 (OMB control number: 0938–1362); *Frequency:* Once and on occasion; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 102; *Total Annual Hours:* 153. (For policy questions regarding this collection contact Ryan Shannahan at 410–786–0295.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Prescription Drug and Health Care Spending; *Use:* On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA) was signed into law. Section 204 of Title II of Division BB of the CAA added parallel provisions at section 9825 of the Internal Revenue Code (the Code), section 725 of the Employee Retirement Income Security Act (ERISA), and section 2799A–10 of the Public Health Service Act (PHS Act) that require group health plans and

health insurance issuers offering group or individual health insurance coverage to annually report to the Department of the Treasury, the Department of Labor (DOL), and the Department of Health and Human Services (HHS) (collectively, ''the Departments'') certain information about prescription drug and health care spending, premiums, and enrollment under the plan or coverage. This information will support the development of public reports that will be published by the Departments on prescription drug reimbursements for plans and coverage, prescription drug pricing trends, and the role of prescription drug costs in contributing to premium increases or decreases under the plans or coverage. The 2021 interim final rules, ''Prescription Drug and Health Care Spending'' issued by the Departments and the Office of Personnel Management (OPM) implement the provisions of section 9825 of the Code, section 725 of ERISA, and section 2799A–10 of the PHS Act, as enacted by section 204 of Title II of Division BB of the CAA. OPM joined the Departments in issuing the 2021 interim final rules, requiring Federal Employees Health Benefits (FEHB) carriers to report information about prescription drug and health care spending, premiums, and plan enrollment in the same manner as a group health plan or health insurance issuer offering group or individual health insurance coverage. *Form Number:* CMS–10788 (OMB control number: 0938–1405); *Frequency:* Annual; *Affected Public:* Private Sector; *Number of Respondents:* 356; *Total Annual Responses:* 356; *Total Annual Hours:* 1,684,080. (For policy questions regarding this collection, contact Christina Whitefield at 301–492–4172.)

Dated: June 23, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–13769 Filed 6–27–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Administration on Disabilities, The President's Committee for People with Intellectual Disabilities

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The President's Committee for People with Intellectual Disabilities (PCPID) will host a virtual meeting for its members to identify emerging topics to examine in the Committee's Report to the President. All the PCPID meetings, in any format, are open to the public. This virtual meeting will be conducted in a presentation and discussion format.

DATES: Thursday, July 28, 2022 from 12:00 p.m. to 4:00 p.m. (EST).

AGENDA: The Committee will discuss survey responses, collectively discuss emerging issues facing people with intellectual disabilities, and the preparation of the PCPID Report to the President, including its proposed content and format, and related data collection and analysis required to complete the writing of the Report.

ADDITIONAL INFORMATION: For further information, please contact Mr. David Jones, Director, Office of Intellectual Developmental Disabilities, 330 C Street SW, Switzer Building, Room 1126, Washington, DC 20201. Telephone: 202–795–7367. Fax: 202–795–7334. Email: *David.Jones@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: Stakeholder input is very important to the PCPID. Comments and suggestions especially from people with intellectual and developmental disabilities, are welcomed. If there are comments or feedback you would like to share with the PCPID as it begins to prioritize its work, please share them through the following *ACL.gov link: https://acl.gov/form/pcpid?j=1555178&sfmc_sub=191090082&l=6707_HTML&u=34777761&mid=5150085 75&jb=0.*

Comments received by June 30, 2022 will be shared with the PCPID at the July 28th meeting. Comments received after June 30, 2022 will be compiled and shared with the PCPID quarterly.

Webinar/Conference Call: The virtual meeting is scheduled for Thursday, July 28, 2022 from 12:00 p.m. to 4:00 p.m. (EST) and may end early if discussions are finished. The meeting will be held through a zoom meeting platform. In order to participate, you must register in advanced of the meeting at the following link: *https://www.zoomgov.com/meeting/register/vJIsdeCpqzgsEiNHISQhI6VBwprCzIlu8BU.*

BACKGROUND INFORMATION ON THE COMMITTEE: The PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services on a broad range of topics relating to programs, services and support for individuals with intellectual disabilities. The PCPID Charter stipulates that the Committee shall: (1) provide such advice concerning intellectual disabilities as the President or the Secretary of Health and Human Services may request; and (2) provide advice to the President and the Secretary of Health and Human Services to promote full participation of people with intellectual disabilities in their communities, such as: (A) expanding educational opportunities; (B) promoting housing opportunities; (C) expanding opportunities for competitive integrated employment; (D) improving accessible transportation options; (E) protecting rights and preventing abuse; and (F) increasing access to assistive and universally designed technologies; and (3) provide advice to the President and the Secretary of Health and Human Services to help advance racial equity and support for people with intellectual disabilities within underserved communities.

Dated: June 22, 2022.

Jill Jacobs,

Commissioner, Administration on Disabilities.

[FR Doc. 2022–13699 Filed 6–27–22; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1496]

Renal Cell Carcinoma: Developing Drugs and Biologics for Adjuvant Treatment; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Renal Cell Carcinoma: Developing Drugs and Biologics for Adjuvant Treatment.'' This guidance is intended to facilitate the development of drugs and biologics for the adjuvant treatment of renal cell carcinoma and provides recommendations for the sponsor on this topic. The guidance includes recommendations regarding eligibility criteria, choice of comparator, followup imaging assessments, determination of disease recurrence, analyses of disease-free survival, and interpretation of trial results. This guidance finalizes the draft guidance of the same title issued on October 2, 2020.

DATES: The announcement of the guidance is published in the **Federal Register** on June 28, 2022.

ADDRESSES: You may submit either electronic or written comments on

Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–D–1496 for ''Renal Cell Carcinoma: Developing Drugs and Biologics for Adjuvant Treatment.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sundeep Agrawal, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2379, Silver Spring, MD 20993–0002, 240–402–4683; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Renal Cell Carcinoma: Developing Drugs and Biologics for Adjuvant Treatment.'' This guidance provides recommendations to sponsors regarding the development of drugs regulated by CDER and CBER for the adjuvant treatment of renal cell carcinoma. The guidance includes recommendations regarding eligibility criteria, choice of comparator, followup imaging assessments, determination of disease recurrence, analyses of disease-free survival (DFS), and interpretation of trial results. Although FDA may consider endpoints other than DFS for the adjuvant treatment of renal cell carcinoma, this guidance is focused on clinical trials with DFS as the primary efficacy endpoint.

Adjuvant renal cell carcinoma clinical trials are an active area of research. There is significant variability in the design, conduct, and analysis of these trials, including the eligibility criteria, radiological disease assessments, the definition of disease recurrence, and the date used to define the DFS endpoint. Consistency in these aspects within and across trials may facilitate interpretation of trial results. These issues were discussed at an FDA-National Cancer Institute public workshop held on November 28, 2017. This final guidance provides recommendations on these issues to facilitate adjuvant renal cell carcinoma clinical trials. This guidance finalizes the draft guidance entitled ''Renal Cell Carcinoma: Developing Drugs and Biologics for Adjuvant Treatment'' issued on October 2, 2020 (85 FR 62310). FDA considered comments received on the draft guidance as the guidance was finalized. The final guidance includes changes to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Renal Cell Carcinoma: Developing Drugs and Biologics for Adjuvant Treatment.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: June 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–13752 Filed 6–27–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1497]

Bladder Cancer: Developing Drugs and Biologics for Adjuvant Treatment; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Bladder Cancer: Developing Drugs and Biologics for Adjuvant Treatment.'' This guidance is intended to facilitate the development of drugs and biologics for the adjuvant treatment of muscle-invasive bladder cancer and provides recommendations for the sponsor on this topic. The guidance includes recommendations regarding eligibility criteria, choice of comparator, followup imaging assessments, determination of disease recurrence, analyses of disease-free survival, and interpretation of trial results. This guidance finalizes the draft guidance of the same title issued on October 1, 2020.

DATES: The announcement of the guidance is published in the **Federal Register** on June 28, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–D–1497 for ''Bladder Cancer: Developing Drugs and Biologics for Adjuvant Treatment.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002 or to the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002.

Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sundeep Agrawal, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2379, Silver Spring, MD 20993–0002, 301–348–3914; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Bladder Cancer: Developing Drugs and Biologics for Adjuvant Treatment.'' This guidance provides recommendations to sponsors regarding the development of drugs regulated by Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research for the adjuvant treatment of muscle-invasive bladder cancer. The guidance includes recommendations regarding eligibility criteria, choice of comparator, followup imaging assessments, determination of disease recurrence, analyses of disease-free survival (DFS), and interpretation of trial results. Although FDA may consider endpoints other than DFS for the adjuvant treatment of muscle-invasive bladder cancer, this guidance is focused on cancer trials with DFS as the primary efficacy endpoint.

Adjuvant muscle-invasive bladder cancer clinical trials are an active area of research. There is significant variability in the design, conduct, and analysis of these trials, including the eligibility criteria, radiological disease assessments, the definition of disease recurrence, and the date used to define the DFS endpoint. Consistency in these aspects within and across trials may facilitate interpretation of trial results. These issues were discussed at an FDA-National Cancer Institute public workshop held on November 28, 2017. This guidance provides recommendations on these issues to facilitate adjuvant muscle-invasive bladder cancer clinical trials. This guidance finalizes the draft guidance entitled ''Bladder Cancer: Developing Drugs and Biologics for Adjuvant Treatment: issued on October 1, 2020 (85 FR 62309). FDA considered comments received on the draft guidance as the guidance was finalized. The final guidance includes changes to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Bladder Cancer: Developing Drugs and Biologics for Adjuvant Treatment.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: June 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–13753 Filed 6–27–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; U24 ATLAS Applications.

Date: July 29, 2022.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NIDDK, Democracy II , 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ryan G. Morris, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, Room 7015, 6707 Democracy Boulevard Bethesda, MD 20892–2542, 301–594–4721, *ryan.morris@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–13700 Filed 6–27–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Eye Disease and Homeostasis.

Date: July 18, 2022.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Prithi Rajan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–1042, *prithi.rajan@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Glioma, Multiple Sclerosis, and Neuroinflammation.

Date: July 20, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Samuel C. Edwards, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435–1246, *edwardss@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Musculoskeletal, Dental, and Oral Sciences.

Date: July 21, 2022.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Chee Lim, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4128, Bethesda, MD 20892, (301) 435–1850, *limc4@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Impact of COVID–19 Pandemic-related Food and Housing Policies in Health Disparity Populations.

Date: July 21, 2022.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kate Fothergill, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive Room 3142, Bethesda, MD 20892, 301–435–1782, *fothergillke@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Social and Community Influences Across the Life Course.

Date: July 21, 2022.

Time: 11:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: David Erik Pollio, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1006F, Bethesda, MD 20892, (301) 594–4002, *polliode@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; HIV and AIDS-Associated Conditions.

Date: July 26, 2022.

Time: 10:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Michelle Marie Arnold, Ph.D., Scientific Review, Officer Center for Scientific, Review National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–435–1199 *michelle.arnold@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: High Throughput Screening.

Date: July 26, 2022.

Time: 11:00 a.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications,

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Michael Eissenstat, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4166, MSC 7806 Bethesda, MD 20892, (301) 435–1722, *eissenstatma@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel Immunity and Host Defense.

Date: July 28, 2022.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Uma Basavanna, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–1199, *uma.basavanna@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 22, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–13702 Filed 6–27–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; NIH Clinical Center Collaboration.

Date: July 12, 2022.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Shanta Rajaram, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, NSC, 6001 Executive Boulevard, Suite 3208, MSC 9529, Bethesda, MD 20852, 301–435–6033, *rajarams@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: June 23, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–13778 Filed 6–27–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Advancing Group A Streptococcus Vaccine Discovery (R01 Clinical Trial Not Allowed).

Date: July 27, 2022.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G53, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Caitlin A. Brennan, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G53, Rockville, MD 20852, (301) 761–7792, *caitlin.brennan2@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: June 23, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–13777 Filed 6–27–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Stress, Psychopathology, Developmental Disabilities, and Substance Use.

Date: July 27, 2022.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rochelle Francine Hentges, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1000C, Bethesda, MD 20892, (301) 402–8720, *hentgesrf@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Motor Function, Pain, and Cognitive Neuroscience.

Date: July 28, 2022.

Time: 12:00 p.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kristen Prentice, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3112, MSC 7808, Bethesda, MD 20892, (301) 496–0726, *prenticekj@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 22, 2022.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–13708 Filed 6–27–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Integrative Research in Gynecologic Health (R01 Clinical Trial Optional).

Date: July 1, 2022.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Eunice Kennedy Shriver, National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2127D, Bethesda, MD 20892 (Video Assisted Meeting).

Contact Person: Luis E. Dettin, Ph.D., MS, MA, Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver, National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Rm. 2127D, Bethesda, MD 20892, (301) 827–8231, *luis_dettin@nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.865, Research for Mothers and Children, National Institutes of Health, HHS)

Dated: June 22, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–13701 Filed 6–27–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Treatment; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given that the

Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT) National Advisory Council (NAC) will meet on August 30, 2022, 12:00 p.m.–4:30 p.m. (EDT).

The meeting is open to the public and will include consideration of minutes from the SAMHSA CSAT NAC meeting of April 27, 2022, a discussion with SAMHSA leadership, and a discussion on the Office of Recovery. It will also cover updates on CSAT activities from the Office of the Director (OD); the Division of Pharmacologic Therapies (DPT); the State Opioid Response Program (SOR); the Division of State and Community Assistance (DSCA); the Division of Services Improvement (DSI), and a discussion on Behavioral Health Workforce.

The meeting will be conducted via Zoom and telephone only and registration is required to participate. Interested persons may present data, information, or views, orally or in writing, on issues pending before the Council. Presentations from the public will be scheduled at the conclusion of the meeting. Individuals interested in making oral presentations must notify the contact person, Tracy Goss, CSAT NAC Designated Federal Officer (DFO) on or before August 12, 2022. Up to three minutes will be allotted for each approved public comment as time permits. Written comments received in advance of the meeting will be considered for inclusion in the official record.

To attend virtually, submit written or brief oral comments, or request special accommodation for persons with disabilities, please register on-line at *https://snacregister.samhsa.gov,* or communicate with the CSAT NAC DFO (see information below).

Meeting information and a roster of Council members may be obtained by accessing the SAMHSA Committee website at *https://www.samhsa.gov/about-us/advisory-councils/csat-national-advisory-council,* or by contacting the DFO.

Council Name: SAMHSA's Center for Substance Abuse Treatment National Advisory Council.

Date/Time/Type: August 30, 2022, 12:00 p.m.–4:30 p.m. EDT, OPEN.

Place: SAMHSA, 5600 Fishers Lane, Rockville, Maryland 20857 (Virtual).

Contact: Tracy Goss, Designated Federal Officer, CSAT National Advisory Council, 5600 Fishers Lane, Rockville, Maryland 20857 (mail), Telephone: (240) 276–0759, Email: *tracy.goss@samhsa.hhs.gov*.

Dated: June 21, 2022.

Carlos Castillo,

Committee Management Officer, SAMHSA.

[FR Doc. 2022–13724 Filed 6–27–22; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2022 Notice of Supplemental Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of intent to award supplemental funding.

SUMMARY: This is a notice of intent to award supplemental funding to the Addiction Technology Transfer Centers (ATTC) Regional Centers and ATTC National Coordinating Office (NCO) recipients funded in FY 2017 under Notice of Funding Opportunities (NOFO) TI–17–005. It will inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) is supporting administrative supplements, which are consistent with the scope of the initial FY 2017 awards, of up to $740,298 each for one-year to the ten ATTC Regional Centers and ATTC NCO for a total funding amount of $8,143,285. These grant recipients were funded in FY 2017 under the ATTC Cooperative Agreements, funding announcement TI–17–005 and have a project end date of September 29, 2022. The supplemental funds will be used to extend the program services for all 11 ATTCs from September 30, 2022 to September 29, 2023. The proposed 12-month extension will allow SAMHSA to align the project periods of the ATTCs with those of the Mental Health Technology Transfer Centers (MHTTC) and Prevention Technology Transfer Centers (PTTC) networks so that all three networks can compete together for the next five-year funding cycle of the Technology Transfer Centers (TTC) program. The TTC program is comprised of the three network programs (ATTC, PTTC and MHTTC), which all use the same training and technical assistance platform. If the three networks are competed in different years and new organizations become award recipients of this cooperative agreement program, the structure of this common platform may be compromised. By competing them at the same time, if changes occur in award recipients, the new award recipients will be able to restructure the website and training platform within the first three months of the new funding cycle without disruptions.

SUPPLEMENTARY INFORMATION:

Funding Opportunity Title: Addiction Technology Transfer Centers (ATTC) Cooperative Agreements NOFO TI–17–005.

Assistance Listing Number: 93.243

Authority: ATTC cooperative agreements are authorized under Section 509 of the Public Health Service Act, as amended.

Justification: Eligibility for this supplemental funding is limited to the ten ATTC Regional Centers and one NCO funded in FY 2017 under the ATTC Cooperative Agreements funding announcement TI–17–005, as they are currently providing regionally-focused treatment and recovery training activities that will continue to be funded through this supplement.

FOR FURTHER INFORMATION CONTACT: Twyla Adams, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, MD 20857, telephone (240) 276–1576; email: *twyla.adams@samhsa.hhs.gov*

Carlos Graham,

Reports Clearance Officer.

[FR Doc. 2022–13616 Filed 6–27–22; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2022–0047]

Port Access Route Study: Approaches to Maine, New Hampshire, and Massachusetts

AGENCY: Coast Guard, DHS.

ACTION: Notification of inquiry and public meetings; request for comments.

SUMMARY: The Coast Guard is seeking additional information related to the notice of study that was published on March 31, 2022, regarding the Approaches to Maine, New Hampshire, and Massachusetts Port Access Route Study (MNMPARS). Following a review of preliminary data and submitted comments, we have identified several areas of additional inquiry related to the study. We invite your comments and responses to the proposed questions and information requests as well as all other comments that address potential impacts to navigation within the area of study.

DATES: Comments and related material must be received on or before August

29, 2022. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Daylight Time on the last day of the comment period.

Although the Coast Guard highly encourages comments and related material to be submitted directly to the electronic docket, five in-person public meetings will be held to provide an opportunity for oral comment on Tuesday, August 2, 2022, from 3 p.m. to 5 p.m., on Wednesday, August 3, 2022, from 3 p.m. to 5 p.m., on Wednesday, August 10, 2022, from 3 p.m. to 5 p.m., on Thursday, August 11, 2022, from 3 p.m. to 5 p.m., and on Wednesday, August 17, 2022, from 3 p.m. to 5 p.m. In addition, a virtual public meeting will also be held on Thursday, August 18, 2022, from 6 p.m. to 8 p.m. via webinar and teleconference to provide an oral comment opportunity for those unable to attend the in-person events. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for more information on the public meeting dates, times, and locations.

ADDRESSES: You may submit comments identified by docket number USCG–2022–0047 using the Federal eRulemaking Portal *http://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this supplemental notice of study, call or email LTJG Thomas Davis, First Coast Guard District (dpw), U.S. Coast Guard; telephone (617) 223–8632, email *SMB-D1Boston-MNMPARS@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

ACPARS Atlantic Coast Port Access Route Study
AIS Automatic Identification System
COMDTINST Commandant Instruction
DHS Department of Homeland Security
EEZ Exclusive Economic Zone
MNMPARS Approaches to Maine, New Hampshire, and Massachusetts Port Access Route Study
MTS Marine Transportation System
PARS Port Access Route Study
TSS Traffic Separation Scheme
USCG United States Coast Guard

II. Background and Purpose

On March 31, 2022, the Coast Guard published a Notice of Study; request for comments entitled ''Port Access Route Study (PARS): Approaches to Maine, New Hampshire, and Massachusetts'' in the **Federal Register** (87 FR 18800). The purpose of the MNMPARS is to evaluate the adequacy of existing vessel routing measures and determine whether additional vessel routing measures are necessary for port approaches to Maine, New Hampshire, and Massachusetts and international and domestic transit areas in the First Coast Guard District area of responsibility. This undertaking is required by 46 U.S.C. 70003, which calls for the Coast Guard to conduct a PARS prior to establishing fairways or traffic separation schemes (TSSs).

The public was afforded a 45-day comment period during which the Coast Guard received 14 comments in response to the **Federal Register** Notice and various other outreach efforts. A review of available data and submitted comments has identified additional opportunities for inquiry that may help inform several aspects of the study.

All comments and supporting documents are available in a public docket and can be viewed at *http://www.regulations.gov.* In the ''Search'' box insert ''USCG–2022–0047'' and click ''Search.'' Then scroll down to and click on the ''notice'' entitled ''Port Access Route Study: Approaches to Maine, New Hampshire, and Massachusetts.'' This will open to the ''Document Details'' page. Then click on the ''Browse Comments'' tab. On the comment tab, you can search and filter comments.

III. Information Requested

The Coast Guard is seeking responses to various *general* and *port specific* questions to gain additional insight into issues impacting regional navigation. Where possible and appropriate, please provide sources or other amplifying information to back up or explain your responses. Also, please provide as much relevant detail as possible when describing your position on a subject and how you've reached your conclusion.

A. *General Questions:* Have maritime community members experienced or do they anticipate any impacts to navigation in the areas within or adjacent to the Gulf of Maine, the New Hampshire Seacoast, or Massachusetts Bay?

1. How will vessel navigation routes change as a result of planned or potential future developments?

2. What current waterway operations affect navigation? In what way?

3. Are there strains on the current vessel routing systems?

4. Are modifications to existing vessel routing measures needed to address hazards and improve efficiency? If so, please describe.

5. Does the maritime community request additional routing measures, other than those that currently exist? Please be as specific as possible.

B. *Port Specific Questions:* Analysis of AIS data suggests several primary vessel traffic patterns are used to access principal ports within the study area. Based on observed traffic density and public comment, the Coast Guard requests the following feedback:

1. Are alternate routes that bypass traffic lanes in the approaches to Portland used as a matter of convenience or hazard avoidance? If so, in what regard? Please be specific.

2. Should the Portland Eastern and Southern Approach TSS be amended to better accommodate inbound/outbound traffic between Portland, Boston, and Canada? In what ways would changes be beneficial or counterproductive?

3. Are additional routing measures needed to provide greater safety for towing vessel traffic transiting offshore of Massachusetts, New Hampshire, and Maine? If so, what type of measures and how would they be beneficial?

4. Are additional routing measures, such as a Northeast Approach TSS, necessary to support Massachusetts Bay/Boston commercial traffic?

5. Is a Navigational Safety Fairway necessary to accommodate vessel traffic from Boston to the Bay of Fundy?

6. Are additional or amendments to current routing measures needed for approaches to other port areas including Eastport, Searsport, and Portsmouth?

IV. Public Participation and Request for Comments

We encourage you to participate in this study by submitting responses to these questions and any other relevant comments and related materials.

A. *Submitting Comments:* To submit your comment online, go to *http://www.regulations.gov,* and insert ''USCG–2022–0047'' in the ''search box.'' Click ''Search''. Then click ''Comment.'' The ''Comment'' button can be found on the following pages:

- Docket Details page when a document within the docket is open for comment,
- Document Details page when the document is open for comment, and
- Document Search Tab with all search results open for comment displaying a ''Comment'' button.

Clicking ''Comment'' on any of the above pages will display the comment form. You can enter your comment on the form, attach files (maximum of 20 files up to 10MB each), and choose whether to identify yourself as an

individual, an organization, or anonymously. Be sure to complete all required fields depending on which identity you have chosen. Once you have completed all required fields and chosen an identity, the ''Submit Comment'' button is enabled. Upon completion, you will receive a Comment Tracking Number for your comment. For additional step by step instructions, please see the Frequently Asked Questions page on *http://www.regulations.gov or by clicking https://www.regulations.gov/faq.*

We accept anonymous comments. Comments we post to *http://www.regulations.gov* will include any personal information you have provided. We review all comments and materials received during the comment period, but we may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

B. *Public Meetings:* The Coast Guard plans to host six public meetings, five in-person and one virtual, to receive oral comments on this notice. If you bring written comments to the in-person public meetings, you may submit them to LTJG Thomas Davis and they will be added to the online public docket. We recommend that you include your name and preferred method of contact in the body of your document so that we can contact you if we have questions regarding your submission. We will provide a written summary of the oral comments received and will place that summary in the docket. The public meeting schedule is as follows:

1. *Portsmouth, NH:* The first public meeting on Tuesday, August 2, 2022, from 3 p.m. to 5 p.m., will be held at the NH Department of Environmental Services, 222 International Drive, Suite 175, Portsmouth, NH 03801.

2. *Salem, MA:* The second public meeting on Wednesday, August 3, 2022, from 3 p.m. to 5 p.m., will be held at the Winter Island Function Hall, 50 Winter Island Road, Salem, MA 01970.

3. *Jonesport, ME:* The third public meeting on Wednesday, August 10, 2022, from 3 p.m. to 5 p.m., will be held at USCG Station Jonesport, 9 Bridge Street, Jonesport, ME 04649.

4. *Belfast, ME:* The fourth public meeting on Thursday, August 11, 2022, from 3 p.m. to 5 p.m., will be held at the University of Maine Hutchinson Center, Conference Room 138, 80 Belmont Avenue, Belfast, ME 04915.

5. *Portland, ME:* The fifth public meeting on Wednesday, August 17, 2022, from 3 p.m. to 5 p.m., will be held at the International Marine Terminal, 454 Commercial Street, Portland, ME 0410.

6. The sixth public meeting will be held virtually via Zoom and teleconference on Thursday, August 18, 2022, from 6 p.m. to 8 p.m.

A link and login instructions for the virtual meeting, as well as additional information regarding the in-person meetings, will be posted to the ''News and Events'' section of the CG Sector Boston Homeport website at *https://homeport.uscg.mil/port-directory/boston* and the CG Sector Northern New England Homeport website at *https://homeport.uscg.mil/port-directory/northern-new-england-(portland-maine),* by July 18, 2022.

C. *How do I find and browse for posted comments on Regulations.gov:* On the previous version of *Regulations.gov,* users browsed for comments on the Docket Details page. However, since comments are made on individual documents, not dockets, new *Regulations.gov* organizes comments under their corresponding document. To access comments and documents submitted to this notice go to *http://www.regulations.gov* and insert ''USCG–2022–0047'' in the ''search box.'' Click ''Search.'' Then scroll down to and click on the ''notice'' entitled ''Port Access Route Study: Notification of inquiry and public meetings; request for comments.'' This will open to the ''Document Details'' page. Then click on the ''Browse Comments'' tab. On the comment tab, you can search and filter comments. Note: If no comments have been posted to a document, the ''Comments'' tab will not appear on the Document Details page.

D. *If you need additional help navigating the new Regulations.gov:* For additional step by step instructions to submit a comment or to view submitted comments or other documents please see the Frequently Asked Questions (FAQs) at *http://www.regulations.gov/faqs* or call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

E. *Privacy Act:* Anyone can search the electronic form of 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 a Privacy Act system of records notice regarding DHS's eRulemaking in the March 11, 2020 issue of the **Federal Register** (85 FR 14226).

This notice is published under the authority of 5 U.S.C. 552(a).

Dated: June 10, 2022.

J.W. Mauger,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

[FR Doc. 2022–13272 Filed 6–27–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6289–N–04]

Withdrawal of Notice of Intent To Establish a Tribal Intergovernmental Advisory Committee; Request for Comments on Committee Structure

AGENCY: Office of the General Counsel (HUD).

ACTION: Withdrawal; notice.

SUMMARY: By this notice HUD is withdrawing a notice published on June 22, 2022, announcing HUD's intention to form the Department's first standing Tribal advisory committee. The June 22, 2022, publication was an erroneous republication of a notice HUD previously published on November 15, 2022. By separate notice published in today's **Federal Register**, HUD is reopening a request for nominations for HUD's Tribal Intergovernmental Advisory Committee (TIAC) for an additional thirty days.

FOR FURTHER INFORMATION CONTACT: Aaron Santa Anna, Associate General Counsel, Legislation and Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10278, Washington, DC 20410–0500, telephone (202) 708–1793 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: On June 22, 2022 (87 FR 37351), HUD erroneously published a notice titled ''Notice of Intent To Establish a Tribal Intergovernmental Advisory Committee; Request for Comments on Committee Structure.'' HUD previously published this notice on November 15, 2022 (86 FR 62051). By today's notice, HUD is withdrawing the June 22, 2022, publication. Elsewhere in today's **Federal Register** HUD is publishing a notice reopening a request for nominations for HUD's Tribal Intergovernmental Advisory Committee (TIAC) for an additional thirty days.

Aaron Santa Anna,

Associate General Counsel for the Office of Legislation and Regulations.

[FR Doc. 2022–13698 Filed 6–27–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6289–N–05]

Tribal Intergovernmental Advisory Committee; Reopening Request for Nominations

AGENCY: Office of Assistant Secretary for Public and Indian Housing, U.S. Department of Housing and Urban Development (HUD).

ACTION: Notice.

SUMMARY: On March 31, 2022, HUD issued a notice seeking requests for nominations for HUD's Tribal Intergovernmental Advisory Committee (TIAC) which closed on May 31, 2022. HUD did not receive any Tribal nominations from the Southwest Region and is reopening the request for nominations for HUD's Tribal Intergovernmental Advisory Committee (TIAC) for another thirty days. HUD encourages nominations from Tribes from all regions. This notice provides details on who is eligible to serve on TIAC and how Tribal governments can nominate persons to serve on TIAC on their behalf.

DATES: Nominations for potential representatives of the TIAC are due on or before July 28, 2022.

ADDRESSES: Interested persons are invited to submit nominations for potential representatives of the TIAC. Nominations must be submitted to HUD electronically. All submissions must refer to the above docket number and title.

Electronic Submission of Nominations. Interested persons must submit nominations electronically through the Federal eRulemaking Portal at *www.regulations.gov* and refer to the above docket number and title. Electronic submission allows the maximum time to prepare and submit nominations, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Nominations submitted electronically through the *www.regulations.gov* website can be viewed by interested members of the public. Individuals should follow the instructions provided on that website to submit nominations.

Note: Nominations should not be submitted by mail.

No Facsimile Comments. Facsimile (FAX) comments will not be accepted.

Public Inspection of Nominations. All properly submitted nominations and communications submitted to HUD will be available for public inspection and copying between 8:00 a.m. and 5:00 p.m. weekdays at the HUD Headquarters building located at 451 7th Street, SW, Washington, DC, 20410–0500. Due to security measures at the HUD Headquarters building, an advance appointment to review the submissions must be scheduled by calling the Regulations Division at (202) 708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the toll-free Federal Relay Service at (800) 877–8339. Copies of all submissions are available for inspection and downloading at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Heidi J. Frechette, Deputy Assistant Secretary for Native American Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW, Room 4108, Washington, DC 20410–0500, telephone (202) 401–7914 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

Consistent with Executive Order 13175,[1] HUD's Tribal Government-to-Government Consultation Policy recognizes the right of Indian tribes to self-governance and supports Tribal sovereignty and self-determination.[2] It provides that HUD will engage in regular and meaningful consultation and collaboration with Tribal officials in the development of Federal policies that have Tribal implications. Executive Order 13175 also requires Federal agencies to advance Tribal self-governance and ensure that the rights of sovereign Tribal governments are fully respected by conducting open and candid consultations. On January 26, 2021, President Biden issued a Presidential Memorandum on Tribal Consultation and Strengthening Nation-to-Nation Relationships.[3] The memorandum directed all Federal agencies to take actions to strengthen their Tribal consultation policies and practices and to further the purposes of Executive Order 13175.

On March 31, 2022, HUD published a notice[4] in the **Federal Register** that provided the revised structure of the TIAC and requested the submission of Tribal nominations to the TIAC. While a sufficient number of nominations were received to fill the Tribal positions, HUD did not receive Tribal nominations from the Southwest Region. To ensure that the TIAC provides sufficient representation, HUD is extending the nomination deadline for TIAC. Nominations are due on or before: July 28, 2022. HUD encourages nominations from Tribes from all regions.

II. Previously Submitted Nominations

Previously submitted nominations do not need to be resubmitted for consideration. These names are already being taken under consideration, along with any other nominations that will be forthcoming under the extension.

III. Nominations for TIAC Representation

HUD is requesting nominations for Tribal representatives to serve on the TIAC. Nominations are due on or before: July 28, 2022. If you are interested in serving as a representative of the Committee or in nominating another person to serve as a representative of the Committee, you may submit a nomination to HUD in accordance with the Electronic Submission of Nominations section of this notice. Your nomination for representation on the Committee must include:

1. The name of the nominee, a description of the interests the nominee would represent, and a description of the nominee's experience and interest in American Indian and Alaska Native housing and community development matters;

2. Evidence that the nominee is a duly elected or appointed Tribal leader and is authorized to represent a federally recognized tribal government or Alaska Native Corporation;

3. A written commitment from the nominee that she or he will actively engage and participate in the Committee meetings; and

4. A written preference for serving either a two- or a three-year term on the TIAC. HUD will appoint the representatives of the TIAC from the pool of nominees submitted in response to this notice. HUD will announce the final selections for TIAC representatives in a subsequent **Federal Register** notice. Representatives will be selected based on proven experience and interest in American Indian and Alaska Native (AIAN) housing and community development matters and whether the interest of the proposed representative could be represented adequately by other representatives. In addition to the

[1] Executive Order 13175, 65 FR 67249 (November 9, 2000).

[2] Tribal Government-to-Government Consultation Policy, 81 FR 40893 (June 23, 2016).

[3] The memorandum was published in the **Federal Register** on January 29, 2021 (86 FR 7491).

[4] Notice of Intent To Establish a Tribal Intergovernmental Advisory Committee; Structure and Request for Nominations, 87 FR 18807 (May 31, 2022).

criteria above, at-large representatives will be selected based on their ability to represent specific interests that might not be represented by the selected regional representatives.

Generally, only elected officers of a tribal government acting in their official capacities with authority to act on behalf of the tribal government may serve as TIAC representatives or alternates of the TIAC. However, tribal employees are also eligible to serve if appointed by a duly elected tribal leader of a federally recognized tribe and are authorized to officially act on the Tribal government's behalf. Elected officials representing Alaska Native Corporations, or designated employees, may also serve on TIAC at HUD's discretion provided they demonstrate that they meet the criteria specified in the statutory exemption to the Federal Advisory Committee Act (FACA) found in the Unfunded Mandates Reform Act (UMRA) at 2 U.S.C. 1534(b).

Because the TIAC will operate under the Tribal government statutory exemption to the Federal Advisory Committee Act (FACA) found in the Unfunded Mandates Reform Act (UMRA) at 2 U.S.C. 1534(b), HUD will not consider nominees solely representing Tribally Designated Housing Entities, state recognized Tribes, or national or regional organizations. However, HUD will consider nominations from associations that represent elected officials of Tribes who have been designated by an elected Tribal leader to participate in TIAC.

Danielle L. Bastarache,

Deputy Assistant Secretary, Office of Public Housing and Voucher Programs; Acting General Deputy Assistant Secretary for the Office of Public and Indian Housing.

[FR Doc. 2022–13697 Filed 6–27–22; 8:45 am]

BILLING CODE 4210–67–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1574 (Final)]

Superabsorbent Polymers From South Korea; Scheduling of the Final Phase of an Antidumping Duty Investigation

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of the final phase of antidumping investigation No. 731–TA–1574 (Final) pursuant to the Tariff Act of 1930 (''the Act'') to determine whether an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of superabsorbent polymers from South Korea, provided for in subheadings 3906.90.50 and 3906.10.00 of the Harmonized Tariff Schedule of the United States, preliminarily determined by the Department of Commerce (''Commerce'') to be sold at less-than-fair-value.

DATES: June 7, 2022.

FOR FURTHER INFORMATION CONTACT: Celia Feldpausch ((202) 205–2387), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Scope.— For purposes of this investigation, Commerce has defined the subject merchandise as superabsorbent polymers (SAP), which is cross-linked sodium polyacrylate most commonly conforming to Chemical Abstracts Service (CAS) registry number 9003–04–7, where at least 90 percent of the dry matter, by weight on a nominal basis, corrected for moisture content, is comprised of a polymer with a chemical formula of $(C_3H_3O_2Na_xH_{1-x})_n$, where *x* is within a range of 0.00–1.00 and there is no limit to *n*. The subject merchandise also includes merchandise with a chemical formula of $\{(C_2H_3)\ COONa_yH_{(1-y)}\}_n$, where *y* is within a range of 0.00–1.00 and there is no limit to *n*. The subject merchandise includes SAP which is fully neutralized as well as SAP that is not fully neutralized.

The subject merchandise may also conform to CAS numbers 25549–84–2, 77751–27–0, 9065–11–6, 9033–79–8, 164715–58–6, 445299–36–5, 912842–45–6, 561012–86–0, 561012–85–9, or 9003–01–4.

All forms and sizes of SAP, regardless of packaging type, including but not limited to granules, pellets, powder, fibers, flakes, liquid, or gel are within the scope of this investigation. The scope also includes SAP whether or not it incorporates additives for anticaking, anti-odor, anti-yellowing, or similar functions.

The scope also includes SAP that is combined, commingled, or mixed with other products after final sieving. For such combined products, only the SAP component is covered by the scope of this investigation. SAP that has been combined with other products is included within the scope, regardless of whether the combining occurs in third countries. A combination is excluded from this investigation if the total SAP component of the combination (regardless of the source or sources) comprises less than 50 percent of the combination, on a nominal dry weight basis.

SAP is classified under the Harmonized Tariff Schedule of the United States (HTSUS) subheading 3906.90.50. SAP may also enter the United States under HTSUS 3906.10.00. Although the HTSUS subheadings and CAS registry numbers are provided for convenience and customs purposes, the written description of the merchandise is dispositive.

Background.—The final phase of this investigation is being scheduled, pursuant to section 735(b) of the Tariff Act of 1930 (19 U.S.C. 1673d(b)), as a result of an affirmative preliminary determination by Commerce that imports of superabsorbent polymers from South Korea are being sold in the United States at less than fair value within the meaning of § 733 of the Act (19 U.S.C. 1673b). The investigation was requested in a petition filed on November 2, 2021, by the Ad Hoc Coalition of American SAP Producers, whose members include BASF Corporation, Florham Park, New Jersey; Evonik Superabsorber LLC, Greensboro, North Carolina; and Nippon Shokubai America Industries, Inc., Pasadena, Texas.

For further information concerning the conduct of this phase of the investigation, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Participation in the investigation and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the final phase of this investigation as parties must file an entry of appearance with the Secretary to the Commission, as provided in § 201.11 of the Commission's rules, no later than 21 days prior to the hearing date specified in this notice. A party

that filed a notice of appearance during the preliminary phase of the investigation need not file an additional notice of appearance during this final phase. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigation.

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*.) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in the final phase of this investigation available to authorized applicants under the APO issued in the investigation, provided that the application is made no later than 21 days prior to the hearing date specified in this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the investigation. A party granted access to BPI in the preliminary phase of the investigation need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the final phase of this investigation will be placed in the nonpublic record on September 29, 2022, and a public version will be issued thereafter, pursuant to § 207.22 of the Commission's rules.

Hearing.—The Commission will hold a hearing in connection with the final phase of this investigation beginning at 9:30 a.m. on October 18, 2022. Information about the place and form of the hearing, including about how to participate in and/or view the hearing, will be posted on the Commission's website at *https://www.usitc.gov/calendarpad/calendar.html.* Interested parties should check the Commission's website periodically for updates. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before October 12, 2022. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference to be held at 9:30 a.m. on October 13, 2022. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party who is an interested party shall submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of § 207.23 of the Commission's rules; the deadline for filing is October 7, 2022. Parties may also file written testimony in connection with their presentation at the hearing, as provided in § 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of section 207.25 of the Commission's rules. The deadline for filing posthearing briefs is October 25, 2022. In addition, any person who has not entered an appearance as a party to the investigation may submit a written statement of information pertinent to the subject of the investigation, including statements of support or opposition to the petition, on or before October 25, 2022. On November 10, 2022, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before November 15, 2022, but such final comments must not contain new factual information and must otherwise comply with § 207.30 of the Commission's rules. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

Additional written submissions to the Commission, including requests pursuant to § 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with §§ 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigation must be served on all other parties to the investigation (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: This investigation is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.21 of the Commission's rules.

By order of the Commission.

Issued: June 22, 2022.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2022–13680 Filed 6–27–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1321]

Certain Barcode Scanners, Scan Engines, Mobile Computers With Barcode Scanning Functionalities, Products Containing the Same, and Components Thereof II; Notice of Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on May 20, 2022, under section 337 of the Tariff Act of 1930, as amended, on behalf of Honeywell International Inc. of Charlotte, North Carolina and Hand Held Products, Inc. of Charlotte, North Carolina. A supplement to the complaint was filed on June 7, 2022. The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain barcode scanners, scan engines, mobile computers with barcode scanning functionalities, products containing the same, and components thereof by reason of the infringement of certain claims of U.S. Patent No. 11,323,649 (''the '649 patent''), U.S. Patent No. 11,323,650 (''the '650 patent''), U.S. Patent No. 7,852,519 (''the '519 patent''), U.S. Patent No. 9,258,188 (''the '188 patent''), and U.S. Patent No. 8,635,309 (''the '309 patent''). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute. The complainants request that the Commission institute an investigation and, after the

investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: Katherine Hiner, Office of Docket Services, U.S. International Trade Commission, telephone (202) 205–1802.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2021).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on June 22, 2022, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1–30 of the '649 patent; claims 1–20 of the '650 patent; claims 1–3, 5–7, and 20 of the '519 patent; claims 1, 2, 5, 6, 9, 11, 12, 16, 19, and 20 of the '188 patent; and claims 1–4, 13, 19–22, 25, 26, 29–32, 40, 42, 47–50, and 57 of the '309 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is ''barcode scanners (also known as barcode readers, barcode decoders, stationary scanners, handheld scanners, companion scanners, cabled scanners, wireless scanners, and mobile scanning devices), handheld computers, mobility devices, scan engines, undecoded scan engines, decoder boards, and imaging modules'';

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

Honeywell International Inc., 855 S Mint Street, Charlotte, NC 28202

Hand Held Products, Inc., 855 S Mint Street, Charlotte, NC 28202

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Zebra Technologies Corporation, 3 Overlook Point, Lincolnshire, IL 60069

Symbol Technologies, Inc., 1 Zebra Plaza, Holtsville, NY 11742

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations will not participate as a party to this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), as amended in 85 FR 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainants of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: June 22, 2022.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2022–13718 Filed 6–27–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1258]

Certain Smart Thermostat Systems, Smart HVAC Systems, Smart HVAC Control Systems, and Components Thereof; Commission Decision To Review in Part a Final Initial Determination; Commission Final Determination Finding No Violation of Section 337; Termination of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review in part a final initial determination (''FID'') of the presiding Administrative Law Judge (''ALJ''). On review, the Commission affirms the FID's finding of no violation of section 337 of the Tariff Act of 1930, as amended, in this investigation. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Houda Morad, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–4716. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On April 2, 2021, the Commission instituted this investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), based on a complaint filed by EcoFactor, Inc. of Palo Alto, California (''Complainant''). *See* 86 FR 17402–03 (Apr. 2, 2021). The complaint, as amended and supplemented, alleges a violation of section 337 based upon the importation into the United States, the sale for

importation, and the sale within the United States after importation of certain smart thermostat systems, smart HVAC systems, smart HVAC control systems, and components thereof by reason of infringement of certain claims of U.S. Patent Nos. 8,423,322 (''the '322 patent''); 8,019,567 (''the '567 patent''); 10,612,983 (''the '983 patent''); 8,596,550 (''the '550 patent''); and 8,886,488 (''the '488 patent''). *See id.* The notice of investigation names the following respondents: ecobee Ltd. and ecobee, Inc. of Toronto, Canada (collectively, ''ecobee''); Google LLC of Mountain View, California (''Google''); Carrier Global Corporation of Palm Beach Gardens, Florida (''Carrier''); Emerson Electric Co. of St. Louis, Missouri (''Emerson''); Honeywell International Inc. of Charlotte, North Carolina (''Honeywell''); Resideo Technologies, Inc. of Austin, Texas (''Resideo''); Johnson Controls International, PLC of Cork, Ireland (''JCP''); and Siemens Industry, Inc. of Buffalo Grove, Illinois and Siemens AG of Munich, Germany (collectively, ''Siemens''). *See id.* The Office of Unfair Import Investigations is not a party to the investigation. *See id.*

The Commission previously terminated the investigation as to respondents Emerson, Siemens, Honeywell, Resideo, and Carrier based on the withdrawal of the allegations in the complaint as to those respondents. *See* Order No. 3 (Apr. 12, 2021), *unreviewed by* Comm'n Notice (Apr. 29, 2021); Order No. 7 (May 13, 2021), *unreviewed by* Comm'n Notice (May 24, 2021); Order No. 13 (July 16, 2021), *unreviewed by* Comm'n Notice (July 30, 2021).

On May 11, 2021, the Commission amended the complaint and notice of investigation to add respondent Johnson Controls Inc. (''JCI'') and to terminate respondent JCP. *See* Order No. 4 (Apr. 20, 2021), *unreviewed by* Comm'n Notice (May 11, 2021). On August 6, 2021, the Commission terminated the investigation as to JCI based on settlement. *See* Order No. 17 (Aug. 6, 2021), *unreviewed by* Comm'n Notice (Aug. 18, 2021). Respondents ecobee and Google (hereinafter, ''Respondents'') remain in this investigation.

On August 18, 2021, the Commission terminated the investigation as to the '322 patent based on the withdrawal of the allegations in the complaint as to that patent. *See* Order No. 16 (Aug. 5, 2021), *unreviewed by* Comm'n Notice (Aug. 18, 2021). On December 8, 2021, the Commission terminated the investigation as to the '567 and '983 patents based on the withdrawal of the allegations in the complaint as to those patents. *See* Order No. 26 (Nov. 8, 2021), *unreviewed by* Comm'n Notice (Dec. 8, 2021). Claims 9 and 17 of the '550 patent and claims 1 and 2 of the '488 patent (collectively, ''the Asserted Patents'') remain in this investigation.

On September 1, 2021, the ALJ issued a claim construction order construing certain terms disputed by the parties before the ALJ. *See* Order No. 18 (Sept 1, 2021). In addition, the ALJ determined that the asserted claims of the '567 patent were invalid as indefinite. *See id.*

On April 4, 2022, the ALJ issued the FID finding no violation of section 337. In particular, the FID finds that Complainant failed to establish infringement of any of the asserted claims of the '550 and '488 patents by the Respondents. In addition, the FID finds all of the asserted claims to be invalid as follows: (1) claims 9 and 17 of the '550 patent and claims 1 and 2 of the '488 patent lack written description under 35 U.S.C. 112 (section 112); and (2) claim 9 (but not claim 17) of the '550 patent and claims 1 and 2 of the '488 patent are patent ineligible under 35 U.S.C. 101 (section 101). The FID also finds that claims 9 and 17 of the '550 patent and claims 1 and 2 of the '488 patent are not invalid as anticipated or obvious under 35 U.S.C. 102 or 103 (section 102 or 103). Furthermore, the FID finds that the technical prong is not satisfied with respect to any of the asserted claims. The FID also finds that the economic prong of the domestic industry requirement is satisfied with respect to both Asserted Patents.

The ALJ's Recommended Determination (''RD'') recommends, should the Commission find a violation of section 337, that the Commission issue a limited exclusion order against smart thermostat systems, smart HVAC systems, smart HVAC control systems, and components thereof imported by or on behalf of the Respondents. The RD does not recommend issuance of a cease and desist order against any of the Respondents. In addition, the RD recommends that the Commission decline to set a bond during the period of Presidential review.

On April 18, 2022, both Complainant and Respondents filed petitions for Commission review of the FID. Complainant petitions for Commission review of the FID's findings on: (1) certain claim constructions; (2) non-infringement; (3) invalidity for lack of written description under section 112; and (4) patent ineligibility under section 101 of claim 9 of the '550 patent and claims 1 and 2 of the '488 patent. Respondents contingently petition for Commission review of the FID's findings on: (1) certain infringement findings; (2) validity of claims 1 and 2 of the '488 patent under section 102 or 103; (3) patent eligibility of claim 17 of the '550 patent under section 101; and (4) the economic prong of the domestic industry requirement. On April 26, 2022, the parties filed responses to each other's petition.

Having examined the record of this investigation, including the FID and the parties' submissions, the Commission has determined to review in part and, upon review, to affirm the FID's determination of no violation of section 337. Specifically, as explained in the Commission Opinion issued concurrently herewith, the Commission has determined to: (1) modify the FID's claim construction findings with respect to the terms ''measurement'' and ''operational efficiency''; (2) affirm with modifications the FID's non-infringement findings as to both Asserted Patents; (3) take no position as to the FID's finding that the technical prong of the domestic industry requirement is not satisfied as to both Asserted Patents; (4) take no position as to the FID's invalidity findings for lack of written description and patent ineligibility as to both Asserted Patents; (5) take no position as to the FID's finding that claim 1 of the '488 patent is not anticipated by U.S. Patent No. 6,478,233 (''Shah'') and that claim 2 of the '488 patent is not obvious over Shah in view of U.S. Patent No. 6,789,739 (''Rosen''); and (6) take no position as to the economic prong of the domestic industry requirement. The Commission adopts all findings in the FID that are not inconsistent with the Commission's determination.

The investigation is terminated.

The Commission's vote for this determination took place on June 22, 2022.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: June 22, 2022.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2022–13717 Filed 6–27–22; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Prohibited Transaction Class Exemption for Security Transactions With Broker-Dealers, Reporting Dealers, and Banks

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Employee Benefits Security Administration (EBSA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before July 28, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Mara Blumenthal by telephone at 202–693–8538, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: Prohibited Transaction Exemption (PTE) 75–1 was granted on October 24, 1975. It consists of five parts covering, among other things, securities transactions between plans and broker-dealers, reporting dealers and banks, as well as other parties. To ensure that the exemption is not abused, that the rights of participants and beneficiaries are protected, and that parties comply with the exemption's conditions, the Department requires limited information collection pertaining to the affected transactions. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on March 17, 2022 (87 FR 15267).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–EBSA.

Title of Collection: Prohibited Transaction Class Exemption for Security Transactions with Broker-Dealers, Reporting Dealers, and Banks.

OMB Control Number: 1210–0092.

Affected Public: Private Sector—Businesses or other for-profits.

Total Estimated Number of Respondents: 5,644.

Total Estimated Number of Responses: 5,644.

Total Estimated Annual Time Burden: 941 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Dated: June 22, 2022.

Mara Blumenthal,

Senior PRA Analyst.

[FR Doc. 2022–13731 Filed 6–27–22; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Prohibited Transaction Exemption for Securities Transactions Involving Employee Benefit Plans and Broker-Dealers

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Employee Benefits Security Administration (EBSA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before July 28, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Mara Blumenthal by telephone at 202–693–8538, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: Prohibited Transaction Class Exemption (PTE) 86–128, which was granted on November 18, 1986, exempts from the prohibited transaction restrictions a fiduciary's use of its authority to cause a plan (including an individual retirement account) or a pooled investment fund to pay a fee to the fiduciary for effecting or executing of securities transactions as agent for the plan or fund. It also permits a fiduciary to act as an agent in an agency cross transaction for both the plan and one or more other parties to the transaction, and to receive reasonable compensation for effecting or executing the agency cross transaction from one or more of the other parties to the transaction. Section III of the class exemption imposes information collection requirements on fiduciaries of employee benefit plans to meet the

conditions of the exemption. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on March 17, 2022 (87 FR 15267).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–EBSA.

Title of Collection: Prohibited Transaction Exemption for Securities Transactions Involving Employee Benefit Plans and Broker-Dealers.

OMB Control Number: 1210–0059.

Affected Public: Private Sector—Businesses or other for-profits and not-for-profit institutions.

Total Estimated Number of Respondents: 8,048.

Total Estimated Number of Responses: 275,745.

Total Estimated Annual Time Burden: 2,193 hours.

Total Estimated Annual Other Costs Burden: $296,108.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Dated: June 22, 2022.

Mara Blumenthal,

Senior PRA Analyst.

[FR Doc. 2022–13730 Filed 6–27–22; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Annual Report for Multiple Employer Welfare Arrangements

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Employee Benefits Security Administration (EBSA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before July 28, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Mara Blumenthal by telephone at 202–693–8538, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The Health Insurance Portability and Accountability Act of 1996 (HIPAA), codified as part 7 of title I of the Employee Retirement Security Act of 1974 (ERISA), was enacted to improve the portability and continuity of health care coverage for participants and beneficiaries of group health plans. HIPAA also added section 101(g) to ERISA, providing the Secretary of Labor with authority to require, by regulation, multiple employer welfare arrangements (MEWAs) as defined in section 3(40) of ERISA, that offer or provide coverage for medical benefits, but which are not group health plans (non-plan MEWAs), to report annually for the purpose of determining compliance with part 7 requirements. While the statutory authority was directed at non-plan MEWAs, based on the authority in ERISA sections 101(g), 505, and 734, DOL in 2003 promulgated a regulation at 29 CFR 2520.101–2 that required the administrators of both plan MEWAs and non-plan MEWAs that offer or provide coverage for medical benefits to file the Form M–1 on an annual basis. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on March 17, 2022 (87 FR 15267).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–EBSA.

Title of Collection: Annual Report for Multiple Employer Welfare Arrangements.

OMB Control Number: 1210–0116.

Affected Public: Private Sector—Businesses or other for-profits and not-for-profit institutions.

Total Estimated Number of Respondents: 719.

Total Estimated Number of Responses: 719.

Total Estimated Annual Time Burden: 1,839 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Dated: June 22, 2022.

Mara Blumenthal,

Senior PRA Analyst.

[FR Doc. 2022–13732 Filed 6–27–22; 8:45 am]

BILLING CODE 4510–29–P

LEGAL SERVICES CORPORATION

Sunshine Act Meetings

TIME AND DATE: The Finance Committee of the Legal Services Corporation's Board of Directors will meet virtually on July 5, 2022. The meeting will commence at 3:00 p.m. EDT and will continue until the conclusion Committee's agenda.

PLACE:

Public Notice of Virtual Meeting.

LSC will conduct the July 5, 2022 meeting via Zoom.

Public Observation: Unless otherwise noted herein, the Finance Committee meeting will be open to public observation via Zoom. 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 Session

July 5, 2022

- To join the Zoom meeting by computer, please use this link.
- *https://lsc-gov.zoom.us/j/84036880893?pwd=SUF3ZWxyblB5TXNDcUJYN0NqM3F3Zz09&from=addon*
  - *Meeting ID:* 840 3688 0893
  - *Passcode:* 7522
- To join the Zoom meeting with one tap from your mobile phone, please click dial:
  - +13017158592,,84036880893# US (Washington DC)
  - +16468769923,,84036880893# US (New York)
- To join the Zoom meeting by telephone, please dial one of the following numbers:
  - +1 301 715 8592 US (Washington DC)
  - +1 646 876 9923 US (New York)
  - +1 312 626 6799 US (Chicago)
  - +1 669 900 6833 US (San Jose)
  - +1 253 215 8782 US (Tacoma)
  - +1 346 248 7799 US (Houston)
  - +1 408 638 0968 US (San Jose)
  - Meeting ID: 840 3688 0893
  - Passcode: 7522

Once connected to Zoom, please immediately mute your computer or telephone. Members of the public are asked to keep their computers or telephones muted to eliminate background noise. To avoid disrupting the meetings, please refrain from placing the call on hold if doing so will trigger recorded music or other sound.

From time to time, the Finance Committee Chair may solicit comments from the public. To participate in the meeting during public comment, use the 'raise your hand' or 'chat' functions in Zoom and wait to be recognized by the Chair before stating your questions and/or comments.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Approval of Meeting Agenda
2. Public Comment Regarding Fiscal Year 2024 Budget Request
3. Consider and Act on Fiscal Year 2024 Budget Request Resolution #2022–XXX
4. Public Comment on Other Matters
5. Consider and Act on Other Business
6. Consider and Act on Adjournment of Meeting

CONTACT PERSON FOR MORE INFORMATION: Jessica Wechter, Special Assistant to the President, at (202) 295–1626. Questions may also be sent by electronic mail to *wechterj@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 *https://www.lsc.gov/about-lsc/board-meeting-materials.*

Dated: June 24, 2022.

Jessica L. Wechter,

Special Assistant to the President, Legal Services Corporation.

[FR Doc. 2022–13920 Filed 6–24–22; 4:15 pm]

BILLING CODE 7050–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

60-Day Notice for the "Blanket Justification for National Endowment for the Arts Funding Application Guidelines and Requirements."

AGENCY: National Endowment for the Arts, National Foundation on the Arts and the Humanities.

ACTION: Notice of proposed collection; comment request.

SUMMARY: The National Endowment for the Arts (NEA), as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995. This program helps to ensure that requested data is provided in the desired format; reporting burden (time and financial resources) is minimized; collection instruments are clearly understood; and the impact of collection requirements on respondents is properly assessed. Currently, the NEA is soliciting comments concerning the proposed information collection of: Blanket Justification for NEA Funding Application Guidelines and Reporting Requirements. A copy of the current information collection request can be obtained by contacting the office listed below in the address section of this notice.

DATES: Written comments must be submitted to the office listed in the address section below within 60 days from the date of this publication in the **Federal Register**. We are particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Can help the agency minimize the burden of the collection of information on those who are to respond, including through the electronic submission of responses.

ADDRESSES: Email comments to Daniel Beattie, Director, Office of Guidelines and Panel Operations, National Endowment for the Arts, at *beattied@arts.gov.*

Dated: June 23, 2022.

Daniel Beattie,

Director, Office of Guidelines and Panel Operations, National Endowment for the Arts.

[FR Doc. 2022–13768 Filed 6–27–22; 8:45 am]

BILLING CODE 7537–01–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request; National Science Foundation Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) Pre-Award Information Collection

AGENCY: National Science Foundation.

ACTION: Notice.

SUMMARY: The National Science Foundation (NSF) is announcing plans to establish this collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, we are providing opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting Office of Management and Budget (OMB) clearance of this collection for no longer than 3 years.

DATES: Written comments on this notice must be received by August 29, 2022 to be assured consideration. Comments received after that date will be considered to the extent practicable. Send comments to address below.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Suite W18200, Alexandria, Virginia 22314; telephone (703) 292–7556; or send email

to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including Federal holidays).

SUPPLEMENTARY INFORMATION:

Title of Collection: National Science Foundation (NSF) Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) Pre-Award Information Collection.

OMB Control No.: 3145–New.

Expiration Date of Approval: Not applicable.

Abstract: The NSF SBIR/STTR programs focus on transforming scientific discovery into products and services with commercial potential and/or societal benefit. Unlike fundamental or basic research activities that focus on scientific and engineering discoveries, the NSF SBIR/STTR programs support the creation of opportunities to move fundamental science and engineering out of the lab and into the market at scale, through startups and small businesses representing deep technology ventures.

The NSF SBIR/STTR programs have two phases: Phase I and Phase II. Phase I is a 6–12 month experimental or theoretical investigation that allows the awardees to determine the scientific and technical feasibility, as well as the commercial merit of the idea or concept. Phase II further develops the proposed concept, with a goal of working toward the commercial launch of the new product, process, or service being developed.

The NSF SBIR/STTR programs request the Office of Management and Budget (OMB) approval of this clearance that will allow the programs to collect information from a selected group of applicants—those that have been reviewed by independent experts and that NSF Program Directors are considering recommending for funding—for the purpose of making a funding decision. This information includes, but is not exclusive to, a list of company officers and the corresponding ownership status of each company officer within the startup, whether the startup is associated or affiliated with other companies, whether there exist any relationships (personal, financial, and/or professional) between project personnel, and the locations of all the facilities where significant research will be performed for the proposed project. Such data will enable the NSF Program Directors to evaluate a given company's business structure, ascertain the level of commitment of the Principal Investigator (PI) and co-PIs to the startup venture, and identify conflicts of interests (if any), as part of the due diligence process that the programs undertake to verify there are no fraudulent or inappropriate business practices prior to recommending the small business for an award.

Following standard OMB requirements, NSF will request OMB approval in advance and provide OMB with a copy of the form containing these questions. Data collected will be used strictly for due-diligence, auditing, and/or legal purposes, and are needed for effective pre-award management, administration, and/or program monitoring. The applicants, if being considered for award, will only be asked to submit a signed form containing their responses to the questions once for *each* NSF SBIR/STTR proposal (Phase I and II, if applicable). The data collection burden to the selected applicants will be limited to no more than 10 minutes of the respondents' time in each instance. Summaries of the collected data are also being used to respond to queries from Congress, the Small Business Administration, the public, NSF's external merit reviewers who serve as advisors, including Committees of Visitors, NSF's Office of the Inspector General, and other pertinent stakeholders

Respondents: PIs listed on the NSF SBIR/STTR proposals.

Estimated Number of Annual Respondents: 750.

Burden on the Public: The overall annualized cost to the respondents is estimated to be $5,500. The following table shows the annualized estimate of costs to PIs who are generally university assistant professors. This estimated hourly rate is based on a report from the American Association of University Professors, ''Annual Report on the Economic Status of the Profession, 2020–21,'' *Academe,* March–April 2021, Survey Report Table 1. According to this report, the average salary of an assistant professor across all types of doctoral-granting institutions was $91,408. When divided by the number of standard annual work hours (2,080), this calculates to approximately $44 per hour.

Respondent type	Number of respondents	Burden hours per respondent	Average hourly rate	Estimated annual cost
PIs	750	0.167	$44	$5,500
Total				5,500

Dated: June 23, 2022.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2022–13728 Filed 6–27–22; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–0320; NRC–2022–0131]

TMI–2 Solutions, LLC; Three Mile Island Station, Unit No. 2

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment request; opportunity to comment, request a hearing, and to petition for leave to intervene; order imposing procedures.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of an amendment to Possession Only License (POL) No. DPR–73, issued to TMI–2 Solutions, LLC (TMI–2 Solutions) for Three Mile Island Station, Unit No. 2 (TMI–2). The NRC received and is considering approval of one amendment request. Pursuant to NRC regulations, TMI–2 Solutions proposes an amendment to the POL for TMI–2. This proposed license amendment request, upon approval, would revise the POL to replace the reference to site physical security, guard training and qualification, and safeguards contingency plans maintained by Unit 1

with a TMI–2 Site Security plan compliant with NRC regulations. For this amendment request, the NRC proposes to determine that it involves no significant hazards consideration (NSHC). Because the amendment request contains sensitive unclassified non-safeguards information (SUNSI), an order imposes procedures to obtain access to SUNSI for contention preparation by persons who file a hearing request or petition for leave to intervene.

DATES: Submit comments by July 28, 2022. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Requests for a hearing or petition for leave to intervene must be filed by August 29, 2022. Any potential party as defined in section 2.4 of title 10 of the *Code of Federal Regulations* (10 CFR) who believes access to SUNSI is necessary to respond to this notice must request document access by July 8, 2022.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0131. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

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

FOR FURTHER INFORMATION CONTACT: Amy Snyder, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301 415–6822, email: *Amy.Snyder@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2022–0131, facility name, unit number(s), docket number(s), application date, and subject when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0131.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. Eastern Time (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2022–0131, facility name, unit number(s), docket number(s), application date, and subject, 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 NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Introduction

The NRC is considering issuance of an amendment to POL No. DPR–73, issued to TMI–2 Solutions for TMI–2 located in Dauphin County, Pennsylvania.

By letter dated May 13, 2021, as supplemented on September 21, 2021, and on March 31, April 28, May 3 (non-public), May 9 (non-public), and May 10, 2022, TMI–2 Solutions submitted a license application request seeking NRC review and approval of modification to License Condition 2.C.(2) for the TMI–2 license in support of the TMI-Station Independent Spent Fuel Installation Only Physical Security Plan. In the March 31 supplement, TMI–2 Solutions stated that TMI–2 Solutions will develop a Security Plan document (its own plan), instead of the site physical security, guard training and qualification, and safeguards contingency plans maintained by Unit 1.

Before issuance of the proposed license amendment, the NRC will need to make the findings required by the Atomic Energy Act of 1954, as amended (the Act), and NRC's regulations.

The NRC has made a proposed determination that the license amendment request involves NSHC. Under the NRC's regulations in 10 CFR 50.92 ''Issuance of amendment,'' this means that operation of the facility in accordance with the proposed amendment would not: (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee provided an analysis of the issue of NSHC. The staff reviewed this analysis and provided its preliminary evaluation of it below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change would revise the TMI–2 POL by revising TMI–2 License Condition 2.C.(2), Physical Protection, to refer to a security plan specific to TMI–2 that is compliant with 10 CFR part 37 ''Physical protection of category 1 and category 2 quantities of radioactive material'' to implement the requirements for 10 CFR 73.67 and part 37 material. During post-defueling monitored storage (PDMS), the activities

occurring at the site and the form of the radiological material present have low safety and security risk profiles, and as such, a significant increase in the probability or consequences of an accident previously evaluated would not be created by the proposed amendment.

TMI–2 plans to transition from PDMS into DECON following the current planning phase and provided this amendment request is approved, and during this phase risks would be further reduced. DECON is one of three decommissioning methods defined by NRC. Once TMI–2 has entered DECON, special nuclear material (SNM) will be retrieved and aggregated to be placed into dry cask storage using various shapes and sizes of containers to place into a basket and canister. To minimize aggregating the remaining SNM, the core debris will be generally packaged and loaded as it is retrieved. These canisters will then be transferred to an expanded Independent Spent Fuel Storage Installation (ISFSI) inside the Three Mile Island Station, Unit No. 1, ISFSI fence to store the canisters after Three Mile Island, Unit 1 (TMI–1) completes their spent fuel transfer campaign to the ISFSI. On-site transfers will utilize storage systems fundamentally similar to those in use by TMI–1 for Spent Fuel (NAC MAGNASTOR). These storage system designs will have been certified by the NRC for such use because they satisfy applicable requirements for safety and security. Using these certified storage systems will assure there are no increases in accident probability or consequences involved with the proposed amendment.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change would revise the TMI–2 POL by revising TMI–2 License Condition 2.C.(2), Physical Protection, and would not create the possibility of a new or different kind of accident from that previously evaluated. When TMI–2 is in the PDMS condition no major decommissioning activities will occur, and there will no longer be any equipment or facilities that need to be protected because there are no designated Target Sets for TMI–2. Based on the above, the NRC preliminarily concludes that during PDMS the proposed amendment would not create the possibility of a new or different kind of accident from any accident previously evaluated.

TMI–2 plans to transition from PDMS into DECON following the current planning phase and provided this amendment request is approved. Once TMI–2 has entered DECON, SNM will be retrieved and aggregated to be placed into dry cask storage using various shapes and sizes of containers to place into a basket and canister. To minimize aggregating the remaining SNM, the core debris will be generally packaged and loaded as it is retrieved. These canisters will then be transferred to an expanded ISFSI inside the TMI–1 ISFSI fence to store the canisters after TMI–1 completes their spent fuel transfer campaign to the ISFSI. On-site transfers will utilize storage systems fundamentally similar to those in use by TMI–1 for Spent Fuel (NAC MAGNASTOR). These storage system designs will have been certified by the NRC for such use because they satisfy applicable requirements for safety and security. This certification assures that no new or different kind of accidents from any accident previously evaluated will be created as a consequence of the proposed amendment.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed change would revise the TMI–2 POL by revising TMI–2 License Condition 2.C.(2), Physical Protection. This change would not involve a significant reduction in a margin of safety for the following reasons. While TMI–2 is in the PDMS, no major decommissioning activities will occur. As stated by NRC in a previous letter dated April 2, 2013, for an exemption from certain security requirements of 10 CFR part 73.55, the NRC determined that the remaining radioactive material is in a form that does not pose a risk of removal and is well dispersed and is not easily aggregated; the potential for radiological sabotage or diversion of SNM at the 10 CFR part 50 licensed site was eliminated; there is no longer any equipment or facilities that need to be protected; and there are no designated Target Sets for TMI Unit 2. Thus, during PDMS, as the potential for radiological sabotage has been eliminated, the requested amendment would not result in a reduction in the margin of safety.

During DECON, to minimize aggregating the remaining SNM, the core debris will be generally packaged and loaded as it is retrieved. SNM will not be aggregated any more than is necessary to load a canister. These canisters will then be transferred to an expanded ISFSI inside the TMI–1 ISFSI fence to store the canisters after TMI–1 completes their spent fuel transfer campaign to the ISFSI. This campaign is scheduled to be completed in the Summer of 2022. Also, on-site transfers will use storage systems fundamentally similar to those in use by TMI–1 for Spent Fuel (NAC MAGNASTOR). These storage system designs will have been certified by the NRC for such use because they satisfy applicable requirements for safety and security. This certification assures that a significant reduction in a margin of safety would not be involved as a consequence of the proposed amendment.

Based on the staff's review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the license amendment request involves NSHC.

The NRC is seeking public comments on this proposed determination that the license amendment request involves NSHC. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day notice period if the Commission concludes the amendment involves NSHC. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period if circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility. If the Commission takes action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. If the Commission makes a final NSHC determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

III. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any persons (petitioner) whose interest may be affected by any of these actions may file a request for a hearing and petition for leave to intervene (petition) with respect to that action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC's regulations

are accessible electronically from the NRC Library on the NRC's public website at *https://www.nrc.gov/reading-rm/doc-collections/cfr.* If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

As required by 10 CFR 2.309(d) the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) the name, address, and telephone number of the petitioner; (2) the nature of the petitioner's right to be made a party to the proceeding; (3) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the petitioner's interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions that the petitioner seeks to have litigated in the proceeding. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner must provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion that support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one that, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii). The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document.

If a hearing is requested, and the Commission has not made a final determination on the issue of NSHC, the Commission will make a final determination on the issue of NSHC. The final determination will serve to establish when the hearing is held. If the final determination is that the amendment request involves NSHC, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission no later than 60 days from the date of publication of this notice. The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document and should meet the requirements for petitions set forth in this section, except that under 10 CFR 2.309(h)(2) a State, local governmental body, or Federally recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. Alternatively, a State, local governmental body, Federally recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a petition is submitted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of his or her position on the issues but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

IV. Electronic Submissions and E-Filing

All documents filed in NRC adjudicatory proceedings including documents filed by an interested State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof that requests to participate under 10 CFR 2.315(c), must be filed in accordance with 10 CFR 2.302. The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases, to mail copies on electronic storage media, unless an exemption permitting an alternative filing method, as further discussed, is granted. Detailed guidance on electronic submissions is located in the ''Guidance for Electronic Submissions to the NRC'' (ADAMS Accession No. ML13031A056) and on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals.html.*

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *Hearing.Docket@nrc.gov,* or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals/getting-started.html.* After a digital ID certificate is obtained and a docket created, the participant must submit adjudicatory documents in Portable Document Format. Guidance on submissions is available on the NRC's

public website at *https://www.nrc.gov/site-help/electronic-sub-ref-mat.html.* A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. ET on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email confirming receipt of the document. The E-Filing system also distributes an email that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed to obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9:00 a.m. and 6:00 p.m., ET, Monday through Friday, except Federal holidays.

Participants who believe that they have good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted in accordance with 10 CFR 2.302(b)–(d). Participants filing adjudicatory documents in this manner are responsible for serving their documents on all other participants. Participants granted an exemption under 10 CFR 2.302(g)(2) must still meet the electronic formatting requirement in 10 CFR 2.302(g)(1), unless the participant also seeks and is granted an exemption from 10 CFR 2.302(g)(1).

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is publicly available at *https://adams.nrc.gov/ehd,* unless excluded pursuant to an order of the presiding officer. If you do not have an NRC-issued digital ID certificate as previously described, click ''cancel'' when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information such as social security numbers, home addresses, or personal phone numbers in their filings unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants should not include copyrighted materials in their submission.

V. Availability of Documents

The documents identified in the following table are available to interested persons through ADAMS.

Document	ADAMS accession No.
Three Mile Island, Unit 2 License Amendment Request—Delete License Condition 2.C.(2) Physical Protection, dated May 13, 2021.	ML21144A262 (non-public, withheld pursuant to 10 CFR 2.390).
Three Mile Island, Unit 2—License Amendment Request—Revised License Condition 2.C.(2) Physical Protection—Supplemental Information, dated September 21, 2021.	ML21267A505.
Three Mile Island Unit 2—Physical Security Plan Response to March18 Supplemental Information Request, dated March 31, 2022.	ML22102A304 (Package).
Three Mile Island 2—Security Plan Proposed Revision License Condition 2.C.(2) (EPID: L-2021–LLA–0103) Proposed License Condition—partial response, dated April 28, 2022.	ML22125A013.
Three Mile Island Nuclear Station, Unit 2 (TMI-2)—Supplemental Letter to Three Mile Island Nuclear Station, Unit 2 (TMI-2)—License Amendment Request—Delete License Condition 2.C.(2) Physical Protection, dated May 9, 2022.	ML22138A281 (non-public, withheld pursuant to 10 CFR 2.390).
Three Mile Island, Unit 2—E-mail from T. Devik, EnergySolutions TMI–2, to A. Snyder, NRC, Physical Security Plan May 9 Submittal Typo Correction, dated May 10, 2022.	ML22131A138.
NRC Letter from L. Camper (NRC) to J. Lash (FirstEnergy Corporation), ''Three Mile Island Nuclear Power Station Unit 2—Issuance of Exemption from Certain Security Requirements of 10 CFR part 73.55 (TAC NO. J00391),'' dated April 2, 2013.	ML112351129.

Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing SUNSI.

B. Within 10 days after publication of this notice of hearing or opportunity for hearing, any potential party who believes access to SUNSI is necessary to respond to this notice may request access to SUNSI. A ''potential party'' is any person who intends to participate as a party by demonstrating standing and filing an admissible contention under 10 CFR 2.309. Requests for access to SUNSI submitted later than 10 days after publication of this notice will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

C. The requestor shall submit a letter requesting permission to access SUNSI to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and provide a copy to the Deputy General Counsel for Licensing, Hearings, and Enforcement, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville,

Maryland 20852. The email addresses for the Office of the Secretary and the Office of the General Counsel are *Hearing.Docket@nrc.gov* and *RidsOgcMailCenter.Resource@nrc.gov,* respectively.[1] The request must include the following information:

(1) A description of the licensing action with a citation to this **Federal Register** notice;

(2) The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in C.(1); and

(3) The identity of the individual or entity requesting access to SUNSI and the requestor's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention.

D. Based on an evaluation of the information submitted under paragraph C, the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding; and

(2) The requestor has established a legitimate need for access to SUNSI.

E. If the NRC staff determines that the requestor satisfies both D.(1) and D.(2), the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order[2] setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.

F. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI must be filed by the requestor no later than 25 days after receipt of (or access to) that information. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.

G. Review of Denials of Access.

(1) If the request for access to SUNSI is denied by the NRC staff after a determination on standing and requisite need, the NRC staff shall immediately notify the requestor in writing, briefly stating the reason or reasons for the denial.

(2) The requestor may challenge the NRC staff's adverse determination by filing a challenge within 5 days of receipt of that determination with: (a) the presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if this individual is unavailable, another administrative judge, or an Administrative Law Judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

(3) Further appeals of decisions under this paragraph must be made pursuant to 10 CFR 2.311.

H. Review of Grants of Access. A party other than the requestor may challenge an NRC staff determination granting access to SUNSI whose release would harm that party's interest independent of the proceeding. Such a challenge must be filed within 5 days of the notification by the NRC staff of its grant of access and must be filed with: (a) the presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if this individual is unavailable, another administrative judge, or an Administrative Law Judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

If challenges to the NRC staff determinations are filed, these procedures give way to the normal process for litigating disputes concerning access to information. The availability of interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether granting or denying access) is governed by 10 CFR 2.311.[3]

I. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI, and motions for protective orders, in a timely fashion in order to minimize any unnecessary delays in identifying those petitioners who have standing and who have propounded contentions meeting the specificity and basis requirements in 10 CFR part 2. The attachment to this Order summarizes the general target schedule for processing and resolving requests under these procedures.

It is so ordered.

Dated: June 23, 2022.

For the Nuclear Regulatory Commission.

Rochelle C. Bavol,

Acting Secretary of the Commission.

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION IN THIS PROCEEDING

Day	Event/activity
0	Publication of **Federal Register** notice of hearing or opportunity for hearing, including order with instructions for access requests.
10	Deadline for submitting requests for access to Sensitive Unclassified Non-Safeguards Information (SUNSI) with information: supporting the standing of a potential party identified by name and address; describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding.
60	Deadline for submitting petition for intervention containing: (i) demonstration of standing; and (ii) all contentions whose formulation does not require access to SUNSI (+25 Answers to petition for intervention; +7 petitioner/requestor reply).

[1] While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC's ''E-Filing Rule,'' the initial request to access SUNSI under these procedures should be submitted as described in this paragraph.

[2] Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

[3] Requestors should note that the filing requirements of the NRC's E-Filing Rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012, 78 FR 34247, June 7, 2013) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as applicable), but not to the initial SUNSI request submitted to the NRC staff under these procedures.

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION IN THIS PROCEEDING—Continued

Day	Event/activity
20	U.S. Nuclear Regulatory Commission (NRC) staff informs the requestor of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows need for SUNSI. (NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents).
25	If NRC staff finds no ''need'' or no likelihood of standing, the deadline for petitioner/requestor to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds ''need'' for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30	Deadline for NRC staff reply to motions to reverse NRC staff determination(s).
40	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Agreement or Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement or Affidavit for SUNSI.
A	If access granted: issuance of presiding officer or other designated officer decision on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3	Deadline for filing executed Non-Disclosure Agreements or Affidavits. Access provided to SUNSI consistent with decision issuing the protective order.
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or notice of opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.
>A + 60	Decision on contention admission.

[FR Doc. 2022–13738 Filed 6–27–22; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95139; File No. SR–ICC–2022–007]

Self-Regulatory Organizations; ICE Clear Credit LLC; Notice of Filing of Proposed Rule Change Relating to the Clearance of Additional Credit Default Swap Contracts

June 22, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934,[1] and Rule 19b–4,[2] notice is hereby given that on June 16, 2022, ICE Clear Credit LLC (''ICC'') 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 primarily by ICC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The principal purpose of the proposed rule change is to revise the ICC Rulebook (the ''Rules'') to provide for the clearance of additional Standard Emerging Market Sovereign CDS contracts (collectively, the ''EM Contracts'').

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICC included statements concerning the purpose of and basis for the proposed rule change, security-based swap submission, or advance notice and discussed any comments it received on the proposed rule change, security-based swap submission, or advance notice. The text of these statements may be examined at the places specified in Item IV below. ICC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

The purpose of the proposed rule change is to adopt rules that will provide the basis for ICC to clear additional credit default swap contracts. ICC proposes to make such change effective following Commission approval of the proposed rule change. ICC believes the addition of these contracts will benefit the market for credit default swaps by providing market participants the benefits of clearing, including reduction in counterparty risk and safeguarding of margin assets pursuant to clearing house rules. Clearing of the additional EM Contracts will not require any changes to ICC's Risk Management Framework or other policies and procedures constituting rules within the meaning of the Securities Exchange Act of 1934 (''Act'').

ICC proposes amending Subchapter 26D of its Rules to provide for the clearance of additional EM Contracts, specifically the Arab Republic of Egypt, Kingdom of Bahrain, and Sultanate of Oman. These additional EM Contracts have terms consistent with the other EM Contracts approved for clearing at ICC and governed by Subchapter 26D of the Rules. Minor revisions to Subchapter 26D (Standard Emerging Market Sovereign (''SES'') Single Name) are made to provide for clearing the additional EM Contracts. Specifically, in Rule 26D–102 (Definitions), ''Eligible SES Reference Entities'' is modified to include Arab Republic of Egypt, Kingdom of Bahrain, and Sultanate of Oman in the list of specific Eligible SES Reference Entities to be cleared by ICC.

(b) Statutory Basis

Section 17A(b)(3)(F) of the Act [3] requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions; to assure the safeguarding of securities and funds which are in the custody or control of ICC or for which it is responsible; and to comply with the provisions of the Act and the rules and regulations thereunder. The additional EM Contracts proposed for clearing are similar to the EM Contracts currently cleared by ICC, and will be cleared pursuant to ICC's existing clearing arrangements and related financial safeguards, protections and risk management procedures. Clearing of the additional EM Contracts will allow market participants an increased ability to manage risk and ensure the safeguarding of margin assets pursuant to clearing house rules. ICC believes that acceptance of the new EM Contracts, on the terms and conditions set out in the Rules, is consistent with the prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts and transactions cleared by ICC, the safeguarding of securities and funds in the custody or control of ICC or for which it is responsible, and the protection of investors and the public interest, within the meaning of Section 17A(b)(3)(F) of the Act.[4]

Clearing of the additional EM Contracts will also satisfy the relevant requirements of Rule 17Ad–22,[5] as set forth in the following discussion.

Rule 17Ad–22(e)(6)(i) [6] requires each covered clearing agency to establish, implement, maintain, and enforce written policies and procedures reasonably designed to cover its credit exposures to its participants by establishing a risk-based margin system that, at a minimum, considers, and produces margin levels commensurate with, the risks and particular attributes of each relevant product, portfolio, and market. In terms of financial resources, ICC will apply its existing margin methodology to the new EM Contracts, which are similar to the EM Contracts currently cleared by ICC. ICC believes that this model will provide sufficient margin requirements to cover its credit exposure to its clearing members from clearing such contracts, consistent with the requirements of Rule 17Ad–22(e)(6)(i).[7]

Rule 17Ad–22(e)(4)(ii) [8] requires each covered clearing agency to establish, implement, maintain, and enforce written policies and procedures reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by maintaining additional financial resources at the minimum to enable it to cover a wide range of foreseeable stress scenarios that include, but are not limited to, the default of the two participant families that would potentially cause the largest aggregate credit exposure for the covered clearing agency in extreme but plausible market conditions. ICC believes its Guaranty Fund, under its existing methodology, will, together with the required initial margin, provide sufficient financial resources to support the clearing of the additional EM Contracts, consistent with the requirements of Rule 17Ad–22(e)(4)(ii).[9]

Rule 17Ad–22(e)(17) [10] requires, in relevant part, each covered clearing agency to establish, implement, maintain, and enforce written policies and procedures reasonably designed to manage its operational risks by (i) identifying the plausible sources of operational risk, both internal and external, and mitigating their impact through the use of appropriate systems, policies, procedures, and controls; and (ii) ensuring that systems have a high degree of security, resiliency, operational reliability, and adequate, scalable capacity. ICC believes that its existing operational and managerial resources will be sufficient for clearing of the additional EM Contracts, consistent with the requirements of Rule 17Ad–22(e)(17),[11] as the new contracts are substantially the same from an operational perspective as existing contracts.

Rule 17Ad–22(e)(8), (9) and (10) [12] requires each covered clearing agency to establish, implement, maintain, and enforce written policies and procedures reasonably designed to define the point at which settlement is final to be no later than the end of the day on which payment or obligation is due and, where necessary or appropriate, intraday or in real time; conduct its money settlements in central bank money, where available and determined to be practical by the Board, and minimize and manage credit and liquidity risk arising from conducting its money settlements in commercial bank money if central bank money is not used; and establish and maintain transparent written standards that state its obligations with respect to the delivery of physical instruments, and establish and maintain operational practices that identify, monitor, and manage the risks associated with such physical deliveries. ICC will use its existing rules, settlement procedures and account structures for the new EM Contracts, which are similar to the EM Contracts currently cleared by ICC, consistent with the requirements of Rule 17Ad–22(e)(8), (9) and (10) [13] as to the finality and accuracy of its daily settlement process and addressing the risks associated with physical deliveries.

Rule 17Ad–22(e)(2)(i) and (v) [14] requires each covered clearing agency to establish, implement, maintain, and enforce written policies and procedures reasonably designed to provide for governance arrangements that are clear and transparent and specify clear and direct lines of responsibility. ICC determined to accept the additional EM Contracts for clearing in accordance with its governance process, which included review of the contract and related risk management considerations by the ICC Risk Committee and approval by its Board. These governance arrangements continue to be clear and transparent, such that information relating to the assignment of responsibilities and the requisite involvement of the ICC Board and committees is clearly detailed in the ICC Rules and policies and procedures, consistent with the requirements of Rule 17Ad–22(e)(2)(i) and (v).[15]

Rule 17Ad–22(e)(13) [16] requires each covered clearing agency to establish, implement, maintain, and enforce written policies and procedures reasonably designed to ensure it has the authority and operational capacity to take timely action to contain losses and liquidity demands and continue to meet its obligations by, at a minimum, requiring its participants and, when practicable, other stakeholders to participate in the testing and review of its default procedures, including any close-out procedures, at least annually and following material changes thereto. ICC will apply its existing default management policies and procedures for

[3] 15 U.S.C. 78q–1(b)(3)(F).

[4] *Id.*

[5] 17 CFR 240.17Ad–22.

[6] 17 CFR 240.17Ad–22(e)(6)(i).

[7] *Id.*

[8] 17 CFR 240.17Ad–22(e)(4)(ii).

[9] *Id.*

[10] 17 CFR 240.17Ad–22(e)(17)(i) and (ii).

[11] *Id.*

[12] 17 CFR 240.17Ad–22(e)(8), (9) and (10).

[13] *Id.*

[14] 17 CFR 240.17Ad–22(e)(2)(i) and (v).

[15] *Id.*

[16] 17 CFR 240.17Ad–22(e)(13).

the additional EM Contracts. ICC believes that these procedures allow for it to take timely action to contain losses and liquidity demands and to continue meeting its obligations in the event of clearing member insolvencies or defaults in respect of the additional single name, in accordance with Rule 17Ad–22(e)(13).[17]

(B) Clearing Agency's Statement on Burden on Competition

ICC does not believe the proposed amendments will have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purposes of the Act. As discussed above, the purpose of the proposed rule change is to adopt rules that will provide the basis for ICC to clear additional credit default swap contracts. The additional EM Contracts will be available to all ICC participants for clearing. The clearing of the additional EM Contracts by ICC does not preclude the offering of the additional EM Contracts for clearing by other market participants. Accordingly, ICC does not believe that clearance of the additional EM Contracts will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed rule change have not been solicited or received. ICC will notify the Commission of any written comments received by ICC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ICC–2022–007 on the subject line.

Paper Comments

Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–ICC–2022–007. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Credit and on ICE Clear Credit's website at *https://www.theice.com/clear-credit/regulation.*

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–ICC–2022–007 and should be submitted on or before July 19, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

J. Matthew DeLesDernier,

Secretary.

[FR Doc. 2022–13707 Filed 6–27–22; 8:45 am]

BILLING CODE 8011–01–P

[17] *Id.*

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–652, OMB Control No. 3235–0699]

Proposed Collection; Comment Request; Extension: Rule 18a–2

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 18a–2 (17 CFR 240.18a–2), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act''). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 18a–2 establishes capital requirements for nonbank major security-based swap participants that are also not registered as broker-dealers (''nonbank MSBSPs''). In particular, a nonbank MSBSP is required at all times to have and maintain positive tangible net worth.

Under Rule 18a–2, nonbank MSBSPs also need to comply with Exchange Act Rule 15c3–4 (17 CFR 240.15c3–4), which requires OTC derivatives dealers and other firms subject to its provisions to establish, document, and maintain a system of internal risk management controls to assist the firm in managing the risk associated with its business activities, including market, credit, leverage, liquidity, legal, and operational risks.

The staff previously estimated that 5 or fewer nonbank entities would register with the Commission as MSBSPs. The staff continues to estimate that 5 or fewer nonbank entities will register with the Commission as MSBSPs, although currently no such entities have registered. These nonbank MSBSPs will be required to establish, document, and regularly review and update risk management control systems with

respect to market, credit, leverage, liquidity, legal and operational risks. Based on similar estimates for OTC derivatives dealers, the Commission staff believes that each nonbank MSBSP will spend approximately 2,000 hours to implement its risk management control system, resulting in a one-time industry-wide hour burden of approximately 10,000 recordkeeping hours, or approximately 3,333 hours per year when annualized over 3 years.[1]

Based on similar estimates for OTC derivatives dealers, the staff further estimates that each of these firms will spend approximately 250 hours per year reviewing and updating its risk management control systems, resulting in an ongoing annual industry-wide hour burden of approximately 1,250 recordkeeping hours per year.[2]

Taken together, the total industry-wide recordkeeping hour burden is approximately 4,583 hours per year.[3]

Because nonbank MSBSPs may not initially have the systems or expertise internally to meet the risk management requirements of Rule 18a–2, these firms will likely hire an outside risk management consultant to assist them in implementing their risk management systems. The staff estimates that each firm will hire an outside management consultant for approximately 200 hours at a cost of approximately $400 per hour, for a one-time external management consulting cost of approximately $80,000 per respondent, and a total one-time industry management consulting cost of approximately $400,000, or approximately $133,333 per year[4] when annualized over 3 years.

Nonbank MSBSPs may incur start-up costs to comply with Rule 18a–2, including information technology costs. The information technology systems of a nonbank MSBSP may be in varying stages of readiness to enable these firms to meet the requirements of Rule 18a–2, so the cost of modifying their information technology systems could vary significantly among firms. Based on estimates for similar collections of information,[5] the Commission staff expects that each nonbank MSBSP will spend an average of approximately $16,000 for one-time initial hardware and software external expenses, for a total one-time industry-wide external information technology cost of approximately $80,000, or approximately $26,667 per year[6] when annualized over 3 years. Based on the estimates for these similar collections of information, the average ongoing external cost to meet the information technology requirements of Rule 18a–2 will be approximately $20,500 per nonbank MSBSP. This will result in an ongoing annual industry-wide external information technology cost of approximately $102,500.[7] Taken together, the total industry-wide information technology related cost burden is approximately $129,167 per year.[8]

Therefore, the total industry-wide recordkeeping cost burden is approximately $262,500 per year ($133,333 + $129,167 = $262,500).

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 by August 29, 2022.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: June 22, 2022.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–13712 Filed 6–27–22; 8:45 am]

BILLING CODE 8011–01–P

[1] 5 MSBSPs × 2,000 hours = 10,000 hours. This one-time burden annualized over a 3-year period is approximately 3,333 hours industry-wide (10,000 hours/3 = 3,333.33 rounded down to 3,333).

[2] 5 MSBSPs × 250 hours/year = 1,250 hours/year.

[3] 2,000 hours/3 years = 3,333.33 + 1,250 hours = 4,583.33 hours rounded down to 4,583.

[4] 5 MSBSPs × 200 hours × $400/hour = $400,000. Annualized over three years, this industry-wide burden is approximately $133,333 per year ($400,000/3 years = $133,333.33 rounded down to $133,333).

[5] *See Risk Management Controls for Broker or Dealers with Market Access,* Exchange Act Release No. 6321 (Nov. 3, 2010), 75 FR 69792, 69814 (Nov. 15, 2010).

[6] 5 MSBSPs × $16,000/3 years = $26,666.666, rounded up to $26,667.

[7] 5 MSBSP × $20,500 = $102,500.

[8] $80,000/3 years + $102,500 = $129,166.667 rounded up to $129,167.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95140; File No. SR–MIAX–2022–23]

Self-Regulatory Organizations: Miami International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 1900, Registration Requirements, Exchange Rule 1903, Continuing Education Requirements, and Exchange Rule 1904, Electronic Filing Requirements for Uniform Forms

June 22, 2022.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 10, 2022, Miami International Securities Exchange, LLC (''MIAX Options'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend Exchange Rule 1903, Continuing Education Requirements. The proposed rule change also makes conforming amendments to Exchange Rule 1900, Registration Requirements. Among other changes, the proposed rule change requires that the Regulatory Element of continuing education be completed annually rather than every three years and provide a path through continuing education for individuals to maintain their qualification following the termination of a registration. The Exchange also proposes to amend its manual signature requirements in Exchange Rule 1904, Electronic Filing Requirements for Uniform Forms.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/,* at MIAX Options' principal office, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Exchange Rules 1900 and 1903. This proposed rule change is based on a filing recently submitted by the Financial Industry Regulatory Authority, Inc. (''FINRA'') [3] and is intended to harmonize the Exchange's registration rules with those of FINRA so as to promote uniform standards across the securities industry.[4] The Exchange also proposes to amend its manual signature requirements in Exchange Rule 1904, Electronic Filing Requirements for Uniform Forms, to align with changes FINRA has made to similar rules.[5] Each change is discussed in detail below.

The proposed changes are based on the changes filed with the Commission in SR–FINRA–2021–003 and SR–FINRA–2021–015.[6] The Exchange proposes to adopt such changes substantially in the same form as proposed by FINRA, with only minor changes necessary to conform to the Exchange's existing rules such as to remove cross-references and rules that are applicable to FINRA members but not to Exchange Members.[7]

[3] *See* Securities Exchange Act Release Nos. 92183 (June 15, 2021), 86 FR 33427 (June 24, 2021) (SR–FINRA–2021–15); *and* 93097 (September 21, 2021), 86 FR 53358 (September 27, 2021) (SR–FINRA–2021–15).

[4] *See, e.g.,* Securities Exchange Act Release Nos. 94400 (March 11, 2022), 87 FR 15286 (March 17, 2022) (SR–NASDAQ–2022–021); 92562 (August 4, 2021), 86 FR 143701 (August 10, 2021) (SR–CBOE–2021–043); 94794 (April 26, 2022), 87 FR 25683 (May 2, 2022) (SR–BOX–2022–016); *and* 94429 (March 16, 2022), 87 FR 16268 (March 22, 2022) (SR–MEMX–2022–05).

[5] *See* Securities Exchange Act Release No. 91262 (March 5, 2021), 86 FR 13935 (March 11, 2021) (SR–FINRA–2021–003).

[6] *See supra* notes 3 and 5.

[7] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

Continuing Education Rules

i. Background

The continuing education program for registered persons of broker-dealers (''CE Program'') currently requires registered persons to complete continuing education consisting of a Regulatory Element and a Firm Element. The Regulatory Element, which is administered by FINRA on behalf of the Exchange, focuses on regulatory requirements and industry standards, while the Firm Element is provided by each firm and focuses on securities products, services, and strategies the firm offers, firm policies, and industry trends. The CE Program is codified under the rules of the self-regulatory organizations (''SROs''). The CE Program for registered persons of Exchange Members is codified under Exchange Rules 1900 and 1903.[8]

a. Regulatory Element

Exchange Rule 1903(a), Regulatory Element, currently requires a registered person to complete the applicable Regulatory Element initially within 120 days after the person's second registration anniversary date, and thereafter, within 120 days after every third registration anniversary date.[9] The Exchange may extend these time frames for good cause shown.[10] Registered persons who have not completed the Regulatory Element within the prescribed time frames will have their Exchange registrations deemed inactive and will be designated as ''CE inactive'' in the CRD system until the requirements of the Regulatory Element have been satisfied.[11] A CE inactive person is prohibited from performing, or being compensated for, any activities requiring Exchange registration, including supervision. Moreover, if registered persons remain CE inactive for two consecutive years, they must requalify by retaking required examinations (or obtain a waiver of the applicable qualification examinations).[12]

The Regulatory Element consists of a subprogram for registered persons generally, and a subprogram for principals and supervisors.[13] While some of the current Regulatory Element content is unique to particular registration categories, most of the content has broad application to both representatives and principals.[14]

The Regulatory Element was originally designed at a time when most individuals had to complete the Regulatory Element at a test center, and its design was shaped by the limitations of the test center-based delivery model. In 2015, FINRA transitioned the delivery of the Regulatory Element to an online platform (''CE Online''), which allows individuals to complete the content online at a location of their choosing, including their private residence. This online delivery provides FINRA with much greater flexibility in updating content in a timelier fashion, developing content tailored to each

[8] *See* Exchange Rules 1900 and 1903.

[9] *See* Exchange Rule 1903(a)(1). An individual's registration anniversary date is generally the date they initially registered with the Exchange in the Central Registration Depository (''CRD®'') system. However, an individual's registration anniversary date would be reset if the individual has been out of the industry for two or more years and is required to requalify by examination, or obtain an examination waiver, in order to reregister. An individual's registration anniversary date would also be reset if the individual obtains a conditional examination waiver that requires them to complete the Regulatory Element by a specified date. Non-registered individuals who are participating in the waiver program under Exchange Rule 1900, Interpretation and Policy .09, Waiver of Examinations for Individuals Working for a Financial Services Industry Affiliate of a Member, (''FSAWP participants'') are also subject to the Regulatory Element. *See also* Exchange Rule 1903(a)(5), Definition of Covered Person. The Regulatory Element for FSAWP participants correlates to their most recent registration(s), and it must be completed based on the same cycle had they remained registered. FSAWP participants are eligible for a single, fixed seven-year waiver period from the date of their initial designation, subject to specified conditions. Registered persons who become subject to a significant disciplinary action, as specified in Exchange Rule 1903(a)(3), Disciplinary Actions, may be required to retake the Regulatory Element within 120 days of the effective date of the disciplinary action, if they remain registered. Further, their cycle for participation in the Regulatory Element may be adjusted to reflect the effective date of the disciplinary action rather than their registration anniversary date.

[10] *See* Exchange Rule 1903(a)(2).

[11] *See id.* Individuals must complete the entire Regulatory Element session to be considered to have ''completed'' the Regulatory Element; partial completion is the same as non-completion.

[12] This CE inactive two-year period is calculated from the date such persons become CE inactive, and it continues to run regardless of whether they terminate their registrations before the end of the two-year period. Therefore, if registered persons terminate their registrations while in a CE inactive status, they must satisfy all outstanding Regulatory Element prior to the end of the CE inactive two-year period in order to reregister with a Member without having to requalify by examination or having to obtain an examination waiver.

[13] The S101 (General Program for Registered Persons) and the S201 (Registered Principals and Supervisors). For more information on both subprograms, *see* Content Outline for the S101 Regulatory Element Program, available at *https://www.finra.org/sites/default/files/S101P_Outline.pdf and* Content Outline for the S201 Regulatory Element Program, available at *https://www.finra.org/sites/default/files/2020-11/s201.pdf.*

[14] The current content is presented in a single format leading individuals through a case that provides a story depicting situations that they may encounter in the course of their work.

registration category and presenting the material in an optimal learning format.

b. Firm Element

Exchange Rule 1903(b), Firm Element, currently requires each firm to develop and administer an annual Firm Element training program for covered registered persons.[15] The rule requires firms to conduct an annual needs analysis to determine the appropriate training.[16] Currently, at a minimum, the Firm Element must cover training in ethics and professional responsibility as well as the following items concerning securities products, services, and strategies offered by the Member: (1) general investment features and associated risk factors; (2) suitability and sales practices considerations; and (3) applicable regulatory requirements.[17]

A firm, consistent with its needs analysis, may determine to apply toward the Firm Element other required training. The current rule does not expressly recognize other required training, such as training relating to the anti-money laundering (''AML'') compliance program,[18] for purposes of satisfying Firm Element training.

c. Termination of a Registration

Currently, individuals whose registrations as representatives or principals have been terminated for two or more years may reregister as representatives or principals only if they requalify by retaking and passing the applicable representative- or principal-level examination or if they obtain a waiver of such examination(s) (the ''two-year qualification period'').[19] The two-year qualification period was adopted prior to the creation of the CE Program and was intended to ensure that individuals who reregister are relatively currently on their regulatory and securities knowledge.

ii. Proposed Rule Change

After extensive work with the Securities Industry/Regulatory Council on Continuing Education (''CE Council'') and discussions with stakeholders, including industry participants and the North American Securities Administrators Association (''NASAA''), FINRA adopted the following changes to the CE Program under its rules.[20] In order to promote uniform standards across the securities industry, the Exchange now proposes to adopt the same changes to its continuing education rules.

a. Transition to Annual Regulatory Element for Each Registration Category

As noted above, currently, the Regulatory Element generally must be completed every three years, and the content is broad in nature. Based on changes in technology and learning theory, the Regulatory Element content can be updated and delivered in a timelier fashion and tailored to each registration category, which would further the goals of the Regulatory Element.[21] Therefore, to provide registered persons with more timely and relevant training on significant regulatory developments, the Exchange proposes to amend Exchange Rule 1903(a) to require registered persons to complete the Regulatory Element annually by December 31.[22] The proposed amendment would also require registered persons to complete the Regulatory Element content for each representative or principal registration category that they hold, which would also further the goals of the Regulatory Element.[23]

Under the proposed rule change, firms would have the flexibility to require their registered persons to complete the Regulatory Element sooner than December 31, which would allow firms to coordinate the timing of the Regulatory Element with other training requirements, including the Firm Element.[24] For example, a firm could require its registered persons to complete both their Regulatory Element and Firm Element by October 1 of each year.

Individuals who would be registering as a representative or principal for the first time on or after the implementation date of the proposed rule change would be required to complete their initial Regulatory Element for that registration category in the next calendar year following their registration.[25] In addition, subject to specified conditions, individuals who would be reregistering as a representative or principal on or after the implementation date of the proposed rule change would also be required to complete their initial Regulatory Element for that registration category in the next calendar year following their reregistration.[26]

Consistent with current requirements, individuals who fail to complete their Regulatory Element within the

[15] ''Covered registered persons'' means any person registered with the Exchange pursuant to Rule 1900, including any person who is permissively registered pursuant to Exchange Rule 1900, Interpretation and Policy .02, and any person who is designated as eligible for a waiver pursuant to Exchange Rule 1900, Interpretation and Policy .09. *See* Exchange Rule 1903(a)(5).

[16] *See* Exchange Rule 1903(b)(2), Standards for the Firm Element.

[17] *Id.*

[18] *See* Exchange Rules 315(e).

[19] *See* Exchange Rule 1900, Interpretation and Policy .08. The two-year qualification period is calculated from the date individuals terminate their registration and the date the Exchange receives a new application for registration. The two-year qualification period does not apply to individuals who terminate a limited registration category that is a subset of a broader registration category for which they remain qualified. For instance, it would not apply to an individual who maintains his registration as a General Securities Representative but who terminates his registration as an Investment Company and Variable Contracts Products Representative. Such individuals have the option of reregistering in the more limited registration category without having to requalify by examination or obtain an examination waiver so long as they continue to remain qualified for the broader registration category. Further, the two-year qualification period only applies to the representative- and principal-level examinations; it does not extend to the Securities Industry Essentials (''SIE'') examination. The SIE examination is valid for four years, but having a valid SIE examination alone does not qualify an individual for registration as a representative or principal. Individuals whose registrations as representatives or principals have been revoked pursuant to Exchange Rule 1011, Judgment and Sanction, may only requalify by retaking the applicable representative- or principal-level examination in order to reregister as representatives or principals, in addition to satisfying the eligibility conditions for association with a firm. Waivers are granted either on a case-by-case basis under Exchange Rule 1900, Interpretation and Policy .03, Qualification Examinations and Waivers of Examinations, or as part of the waiver program under Exchange Rule 1900, Interpretation and Policy .09.

[20] *See* supra note 3. FINRA's changes are based on the CE Council's September 2019 recommendations to enhance the CE Program. *See* Recommended Enhancements for the Securities Industry Continuing Education Program, available at *http://cecouncil.org/media/266634/council-recommendations-final-.pdf.* The CE Council is composed of securities industry representatives and representatives of SROs. The CE Council was formed in 1995 upon a recommendation from the Securities Industry Task Force on Continuing Education and was tasked with facilitating the development of uniform continuing education requirements for registered persons of broker-dealers.

[21] When the CE Program was originally adopted in 1995, registered persons were required to complete the Regulatory Element on their second, fifth and tenth registration anniversary dates. *See* Securities Exchange Act Release No. 35341 (February 8, 1995), 60 FR 8426 (February 14, 1995) (Order Approving File Nos. SR–AMEX–94–59; SR–CBOE–94–49; SR–CHX–94–27; SR–MSRB–94–17; SR–NASD–94–72; SR–NYSE–94–43; SR–PSE–94–35; and SR–PHLX–94–52). The change to the current three-year cycle was made in 1998 to provide registered persons more timely and effective training, consistent with the overall purpose of the Regulatory Element. *See* Securities Exchange Act Release No. 39712 (March 3, 1998), 63 FR 11939 (March 11, 1998) (Order Approving File Nos. SR–CBOE–97–68; SR–MSRB–98–02; SR–NASD–98–03; and SR–NYSE–97–33).

[22] *See* proposed changes to Exchange Rules 1903(a)(1) and (a)(4).

[23] *See* proposed changes to Exchange Rules 1900, Interpretation and Policy .07, *and* 1903(a)(1).

[24] *See* proposed changes to Exchange Rules 1903(a)(1) and (a)(4).

[25] *See* proposed changes to Exchange Rule 1903(a)(1).

[26] *See* proposed changes to Exchange Rule 1903(a)(4).

prescribed period would be automatically designated as CE inactive.[27] However, the proposed rule change preserves the Exchange's ability to extend the time by which a registered person must complete the Regulatory Element for good cause shown.[28]

The Exchange also proposes to amend Exchange Rule 1903(a) to clarify that: (1) individuals who are designated as CE inactive would be required to complete all of their pending and upcoming annual Regulatory Element, including any annual Regulatory Element that becomes due during their CE inactive period, to return to active status; [29] (2) the two-year CE inactive period is calculated from the date individuals become CE inactive, and it continues to run regardless of whether individuals terminate their registrations; [30] (3) individuals who become subject to a significant disciplinary action may be required to complete assigned continuing education content as prescribed by the Exchange; [31] (4) individuals who have not completed any Regulatory Element content for a registration category in the calendar year(s) prior to reregistering would not be approved for registration for that category until they complete that Regulatory Element content, pass an examination for that registration category or obtain an unconditional examination waiver for that registration category, whichever is applicable; [32] and (5) the Regulatory Element requirements apply to individuals who are registered, or in the process of registering, as a representative or principal.[33] In addition, the Exchange proposed making conforming amendments to Exchange Rule 1900, Interpretation and Policy .07.

Under the proposed rule change, the amount of content that registered persons would be required to complete in a three-year, annual cycle for a particular registration category is expected to be comparable to what most registered persons are currently completing every three years. In some years, there may be more required content for some registration categories depending on the volume of rule changes and regulatory issues. In addition, an individual who holds multiple registrations may be required to complete additional content compared to an individual who holds a single registration because, as noted above, individuals would be required to complete content specific to each registration category that they hold.[34] However, individuals with multiple registrations would not be subject to duplicative regulatory content in any given year. The more common registration combinations would likely share much of their relevant regulatory content each year. For example, individuals registered as General Securities Representatives and General Securities Principals would receive the same content as individuals solely registered as General Securities Representatives, supplemented with a likely smaller amount of supervisory-specific content on the same topics. The less common registration combinations may result in less topic overlap and more content overall.

b. Recognition of Other Training Requirements for Firm Element and Extension of Firm Element to All Registered Persons

To better align the Exchange's Rulebook with FINRA's Rulebook, and, in addition, to better align the Firm Element requirement with other required training, the Exchange proposes amending Rule 1903(b) to expressly allow firms to consider training relating to the AML compliance program and the annual compliance meeting toward satisfying an individual's annual Firm Element requirement.[35] The Exchange also proposes to amend the rule to extend the Firm Element requirement to all registered persons, including individuals who maintain solely a permissive registration consistent with Exchange Rule 1900, Interpretation and Policy .02, Permissive Registrations, thereby further aligning the Firm Element requirement with other broadly-based training requirements.[36] In conjunction with this proposed change, the Exchange proposes modifying the current minimum training criteria under Exchange Rule 1903(b) to instead provide that the training must cover topics related to the role, activities, or responsibilities of the registered person and to professional responsibility.[37]

c. Maintenance of Qualification After Termination of Registration

The Exchange proposes adopting paragraph (c) under Exchange Rule 1903 and Interpretation and Policies .01 and .02 to Exchange Rule 1903 to provide eligible individuals who terminate any of their representative or principal registrations the option of maintaining their qualification for any of the terminated registrations by completing continuing education.[38] The proposed rule change would not eliminate the two-year qualification period. Rather, it would provide such individuals as alternative means of staying current on their regulatory and securities knowledge following the termination of a registration(s). Eligible individuals who elect not to participate in the proposed continuing education program would continue to be subject to the current two-year qualification period. The proposed rule change is generally aligned with other professional continuing education programs that allow individuals to maintain their qualification to work in their respective fields during a period of absence from their careers (including an absence of more than two years) by satisfying continuing education requirements for their credential.

The proposed rule change would impose the following conditions and limitations:

- Individuals would be required to be registered in the terminated registration category for at least one year

[27] *See* proposed changes to Exchange Rule 1903(a)(2).

[28] *See id.* The proposed rule change clarifies that the request for an extension of time must be in writing and include supporting documentation, which is consistent with current practice.

[29] *Id.*

[30] *Id.*

[31] *See* proposed changes to Exchange Rule 1903(a)(3). As previously noted, Exchange Rule 1903(a)(3) currently provides that such individuals may be required to retake the Regulatory Element. *See supra* note 9.

[32] *See* proposed changes to Exchange Rule 1903(a)(4).

[33] *See* proposed changes to Exchange Rule 1903(a)(5).

[34] As discussed in the Economic Impact Assessment section in the FINRA Rule Change, *supra* note 3, individuals with multiple registrations represent a small percentage of the population of registered persons.

[35] *See* proposed Exchange Rule 1903(b)(2)(iv).

[36] *See* proposed changes to Exchange Rule 1903(b)(1). As noted earlier, the current requirement only applies to ''covered registered persons'' and not all registered persons.

[37] *See* proposed changes to Exchange Rule 1903(b)(2)(ii).

[38] The proposed option would also be available to individuals who terminate any permissive registrations as provided under Exchange Rule 1900, Interpretation and Policy .02. However, the proposed option would not be available to individuals who terminate a limited registration category that is a subset of a broader registration category for which they remain qualified. As previously noted, such individuals currently have the option of reregistering in the more limited registration category without having to requalify by examination or obtain an examination waiver so long as they continue to remain qualified for the broader registration category. In addition, the proposed option would not be available to individuals who are maintaining an eliminated registration category, such as the category for Corporate Securities Representative, or individuals who have solely passed the Securities Industry Essentials examination, which does not, in and of itself, confer registration.

immediately prior to the termination of that category; [39]

- Individuals could elect to participate when they terminate a registration or within two years from the termination of a registration; [40]
- Individuals would be required to complete annually all prescribed continuing education; [41]
- Individuals would have a maximum of five years in which to reregister; [42]
- Individuals who have been CE inactive for two consecutive years, or who become CE inactive for two consecutive years during their participation, would not be eligible to participate or continue; [43] and
- Individuals who are subject to a statutory disqualification, or who become subject to a statutory disqualification following the termination of their registration or during their participation, would not be eligible to participate or continue.[44]

The proposed rule change also includes a look-back provision that would, subject to specified conditions, extend the proposed option to individuals who have been registered as a representative or principal within two years immediately prior to the implementation date of the proposed rule change and individuals who have been FSAWP participants immediately prior to the implementation date of the proposed rule change.[45]

In addition, the proposed rule change includes a re-eligibility provision that would allow individuals to regain eligibility to participate each time they reregister with a firm for a period of at least one year and subsequently terminate their registration, provided that they satisfy the other participation conditions and limitations.[46] Finally, the Exchange proposes making conforming amendments to Exchange Rule 1900, including adding references to proposed Exchange Rule 1903(c) and Interpretation and Policy .08 to Exchange Rule 1900.

The proposed rule change will have several important benefits. It will provide individuals with flexibility to address life and career events and necessary absences from registered functions without having to requalify each time. It will also incentivize them to stay current on their respective securities industry knowledge following the termination of any of their registrations. The continuing education under the proposed option will be as rigorous as the continuing education of registered persons, which promotes investor protection. Further, the proposed rule change will enhance diversity and inclusion in the securities industry by attracting and retaining a broader and diverse group of professionals.

Significantly, the proposed rule change will be of particular value to women, who continue to be the primary caregivers for children and aging family members and, as a result, are likely to be absent from the industry for longer periods.[47] In addition, the proposed rule change will provide longer-term relief for women, individuals with low incomes and other populations, including older workers, who are at a higher risk of a job loss during certain economic downturns and who are likely to remain unemployed for longer periods.[48]

d. CE Program Implementation

As stated in the FINRA Rule Change, FINRA and the CE Council also plan to enhance the CE Program in other ways, and these additional enhancements do not require any changes to the FINRA

[39] *See* proposed Exchange Rule 1903(c)(1).

[40] *See* proposed Exchange Rule 1903(c)(2). Individuals who elect to participate at the later date would be required to complete, within two years from the termination of their registration, any continuing education that becomes due between the time of their Form U5 (Uniform Termination Notice for Securities Industry Registration) submission and the date that they commence their participation. In addition, FINRA would enhance its systems to notify individuals of their eligibility to participate, enable them to affirmatively opt in, and notify them of their annual continuing education requirement if they opt in.

[41] *See* proposed Exchange Rule 1903(c)(3). However, upon a participant's request and for good cause shown, the Exchange would have the ability to grant an extension of time for the participant to complete the prescribed continuing education. A participant who is also a registered person must directly request an extension of the prescribed continuing education from the Exchange. The continuing education content for participants would consist of a combination of Regulatory Element content and content selected by FINRA and the CE Council from the Firm Element content catalog. The content would correspond to the registration category for which individuals wish to maintain their qualifications. Participants who are maintaining their qualification status for a principal registration category that includes one or more co-requisite representative registrations must also complete required annual continuing education for the co-requisite registrations in order to maintain their qualification status for the principal registration category. The proposed rule change clarifies that the prescribed continuing education must be completed by December 31 of the calendar year, which is consistent with the timing for the proposed annual Regulatory Element.

[42] *See* proposed Exchange Rule 1903(c). In addition, individuals applying for reregistration must satisfy all other requirements relating to the registration process (*e.g.,* submit a Form U4 (Uniform Application for Securities Industry Registration or Transfer) and undergo a background check).

[43] *See* proposed Exchange Rules 1903(c)(4) *and* (c)(5).

[44] *See* proposed Exchange Rules 1903(c)(1) *and* (c)(6). Further, any content completed by participants would be retroactively nullified upon disclosure of the statutory disqualification. The following example illustrates the application of the proposed rule change to individuals who become subject to a statutory disqualification while participating in the proposed continuing education program. Individual A participates in the proposed continuing education program for four years and completes the prescribed content for each of those years. During year five of his participation, he becomes subject to a statutory disqualification resulting from a foreign regulatory action. In that same year, the Exchange receives a Form U4 submitted by a Member on behalf of Individual A requesting registration with the Exchange. The Form U4 discloses the statutory disqualification event. The Exchange would then retroactively nullify any content that Individual A completed while participating in the proposed continuing education program. Therefore, in this example, in order to become registered with the Exchange, he would be required to requalify by examination. This would be in addition to satisfying the eligibility conditions for association with an Exchange Member firm. *See* Exchange Act Sections 3(a)(39) and 15(b)(4).

[45] *See* proposed Exchange Rule 1903, Interpretation and Policy .01. Such individuals would be required to elect whether to participate by the implementation date of the proposed rule change. If such individuals elect to participate, they would be required to complete their initial annual content by the end of the calendar year in which the proposed rule change is implemented. In addition, if such individuals elect to participate, their initial participation period would be adjusted based on the date that their registration was terminated. The current waiver program for FSAWP participants would not be available to new participants upon implementation of the proposed rule change. *See* proposed Exchange Rule 1900, Interpretation and Policy .09. However, individuals who are FSAWP participants immediately prior to the implementation date of the proposed rule change could elect to continue in that waiver program until the program has been retired. As noted above, FSAWP participants may participate for up to seven years in that waiver program, subject to specified conditions. *See* supra note 9. As discussed above, the proposed rule change provides a five-year participation period for participants in the proposed continuing education program. So as not to disadvantage FSAWP participants, the Exchange has determined to preserve that waiver program for individuals who are participating in the FSAWP immediately prior to the implementation date of the proposed rule change. Because the proposed rule change transitions the Regulatory Element to an annual cycle, FSAWP participants who remain in that waiver program following the implementation of the proposed rule change would be subject to an annual Regulatory Element requirement. *See* proposed changes to Exchange Rule 1903(a)(1). Finally, the proposed rule change preserves the Exchange's ability to extend the time by which FSAWP participants must complete the Regulatory Element for good cause shown. *See* proposed changes to Exchange Rule 1903(a)(2).

[46] *See* proposed Exchange Rule 1903, Interpretation and Policy .02.

[47] *See* The Female Face of Family Caregiving (November 2018), available at *https://www.nationalpartnership.org/our-work/resources/economic-justice/female-face-family-caregiving.pdf.*

[48] The COVID–19 Recession Is the Most Unequal in Modern U.S. History (September 30, 2020), available at *https://www.washingtonpost.com/graphics/2020/business/coronavirus-recession-equality/* and Unemployment's Toll on Older Workers Is Worst in Half a Century (October 21, 2020), available at *https://www.aarp.org/work/working-at-50-plus/info-2020/pandemic-unemployement-older-workers.*

rules.[49] As it relates to the rule changes themselves, the changes relating to the Maintaining Qualifications Program (proposed paragraph (c) of Exchange Rule 1903, and Interpretations and Policies .01 and .02) and the Financial Services Affiliate Waiver Program (FSAWP) (Interpretation and Policy .09 to Exchange Rule 1900) will be implemented July 1, 2022. All other changes related to the FINRA Rule Change, including the changes relating to the Regulatory Element, Firm Element and the two-year qualification period, will be implemented January 1, 2023.[50]

Manual Signature

Exchange Rule 1904(c) currently provides that every initial and transfer electronic Form U4 filing and any amendments to the disclosure information on Form U4 must be based on a manually signed Form U4 provided to the Member or applicant for membership by the person on whose behalf the Form U4 is being filed, consistent with FINRA Rule 1010(c). Similarly, Exchange Rule 1904, Interpretation and Policy .03, currently provides that in the event a Member is not able to obtain an associated person's manual signature or written acknowledgement of amended disclosure information on that person's Form U4 prior to filing on such amendment reflecting the information pursuant to proposed Exchange Rule 1903(c)(3), the Member must enter ''Representative Refused to Sign/ Acknowledge'' or ''Representative Not Available'' or a substantially similar entry in the electronic Form U4 field for the associated person's signature. However, FINRA has since amended their Rule 1010(c) to permit firms to choose to rely on electronic signatures to satisfy the signature requirements when filing Form U4.[51] Several other exchanges have also updated their rules to reflect FINRA's updated Rule 1010(c).[52]

The Exchange proposes to amend Exchange Rule 1904(c) and Interpretation and Policy .03 to similarly allow firms to rely on electronic signatures when filing Form U4, consistent with FINRA Rule 1010(c). Specifically, the Exchange proposes to remove the term ''manual'' from ''manual signature'' and the term ''manually'' from ''manually signed.'' The proposed rule change provides Members, and applicants for membership, with an opportunity to better manage operational challenges. Particularly, the COVID–19 pandemic amplified the need to better manage operational challenges like those that arose during the pandemic and that may continue to arise in the future. Additionally, the proposed rule change would not require the use of a particular type of technology to obtain a valid electronic signature from the associated person. The Exchange believes that some firms may be unable to obtain the manual signature of applicants for registration resulting in a significant operational backlog. By permitting these firms to rely on electronic signatures to satisfy the signature requirements of Exchange Rule 1904(c) and Interpretation and Policy .03, the proposed rule change may reduce or eliminate this backlog. For purposes of the proposed rule change, a valid electronic signature would be any electronic mark that clearly identifies the signatory and is otherwise in compliance with the Electronic Signatures in Global and National Commerce Act (''E-Sign Act'') and the guidance issued by the Commission relating to the E-Sign Act.[53]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[54] in general, and furthers the objectives of Section 6(b)(5) of the Act,[55] in particular, in that it is designed to prevent fraudulent and manipulative practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

As noted above, the proposed rule changes seek to align the Exchange Rules with recent changes to FINRA rules.[56] The Exchange believes the proposed rule changes are consistent with the provisions of Section 6(b)(5) of the Act,[57] which requires, among other things, that Exchange Rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest, and Section 6(c)(3) of the Act,[58] which authorizes the Exchange to prescribe standards of training, experience, and competence for persons associated with the Exchange. The Exchange is proposing to adopt such changes substantially in the same form proposed by FINRA with only minor changes necessary to conform to the Exchange's existing rules, such as removal of cross-references to rules that are applicable to FINRA members but not Members of the Exchange.[59] The Exchange believes the proposal is consistent with the Act for the reasons described above.

The Exchange believes the proposed changes to the Regulatory Element will ensure that all Registered Representatives receive timely and relevant training, which will, in turn, enhance compliance and investor protection. The Exchange believes that establishing a path for individuals to maintain their qualification following the termination of a registration will reduce unnecessary impediments to requalification and promote greater diversity and inclusion in the securities industry without diminishing investor protection.

As it relates to the proposed changes to Exchange Rule 1904(c), the Exchange believes the proposed rule change provides firms with the flexibility to rely on electronic signatures to satisfy the signature requirements of Exchange Rule 1904(c). Specifically, the Exchange proposes to amend Exchange Rule 1904(c) and Interpretation and Policy .03, similar to the amendments made by FINRA, to provide the option of filing an initial or a transfer Form U4 based on a manually or an electronically signed copy of the form provided to the Member, or applicant for membership, by the individual on whose behalf the form is being filed. Considering the

[49] *See supra* note 3. Similar to FINRA, these additional enhances do not require any changes to Exchange Rules.

[50] *See* FINRA Regulatory Notice 21–41 at *https://www.finra.org/rules-guidance/notices/21-41*.

[51] *See supra* note 5.

[52] *See e.g.,* Securities Exchange Act Release Nos. 94400 (March 11, 2022), 87 FR 15286 (March 17, 2022) (SR–NASDAQ–2022–021); 92562 (August 4, 2021), 86 FR 143701 (August 10, 2021) (SR–CBOE–2021–043); *and* 94794 (April 26, 2022), 87 FR 25683 (May 2, 2022) (SR–BOX–2022–016).

[53] *See accord* Securities Exchange Act Release No. 85282 (March 11, 2019), 84 FR 9573 (March 15, 2019) (Order Approving File No. SR–FINRA–2018–040) (discussing valid electronic signatures under existing guidance).

[54] 15 U.S.C. 78f(b).

[55] 15 U.S.C. 78f(b)(5).

[56] *See supra* note 3.

[57] 15 U.S.C. 78f(b)(5).

[58] 15 U.S.C. 78f(c)(3).

[59] Proposed changes to Interpretation and Policy .08 of Exchange Rule 1900 is based on and substantially similar to FINRA Rule 1210.08. The proposed changes to Exchange Rule 1903(a)(1)–(4), proposed changes to Exchange Rule 1903(b), proposed Exchange Rule 1903(c), and proposed Interpretations and Policies .01–.02 to Exchange Rule 1903(c) are based on and substantially similar to FINRA Rules 1240(a)(1)–(4), FINRA Rule 1240(b), FINRA Rule 1240(c) and Supplementary Materials .01 and .02 to FINRA Rule 1240. The Exchange does not currently have a provision analogous to FINRA Rule 3110 and thus has omitted language referring to such provision in its proposed Rules.

technological advancements that provide for enhanced authentication and security of electronic signatures, the Exchange believes that it is appropriate to amend Exchange Rule 1904(c) and Interpretation and Policy .03 to provide such flexibility. The proposed rule change also addresses the ongoing public health risks stemming from the outbreak of COVID–19 and the operational challenges that firms continue to face as a result of pandemic repercussions. By permitting these firms to rely on electronic signatures to satisfy the signature requirements of Exchange Rule 1904(c) and Interpretation and Policy .03, the proposed rule change may reduce or eliminate an operational backlog due to the difficulty firms may have faced in obtaining the manual signature of applicants for registration as a result of the impact of the pandemic on daily work environments. The Exchange believes the proposal is consistent with the Act for the reasons described above and for the reasons outlined in the recent filings SR–FINRA–2021–003 and SR–FINRA–2021–015.[60]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. All Members would be subject to the proposed rule change. The proposed rule change relating to the Exchange's CE Program, which is materially identical to the FINRA Rule Change, is designed to result in a more efficient CE Program that addresses relevant regulatory requirements and provides individuals with improved tools and resources to understand and comply with such requirements, enhancing investor protection. Moreover, the proposed rule change would provide new channels for individuals to maintain their qualification status for a terminated registration category and, in so doing, could increase the likelihood that professionals who need to step away from the industry for a period could return, subject to satisfying all other requirements relating to the registration process.

As it relates to the proposed amendments to Exchange Rule 1904(c), the proposed rule change relating to manual signatures is, in all material respects, substantively identical to a recent rule change adopted by FINRA. The Exchange believes the proposed change will reduce a regulatory filing burden for Members by allowing them to rely on Form U4 copies with an electronic signature. All Members will have the option to rely on such forms with an electronic signature (or continue to rely on forms with a manual signature).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[61] and Rule 19b–4(f)(6) thereunder.[62]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii), the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that this proposed rule change may become operative immediately upon filing. In addition, Rule 19b–4(f)(6)(iii)[63] requires a self-regulatory organization to give the Commission written notice of its intent to file a proposed rule change under that subsection at least five business days prior to the date of filing, or such shorter time as designated by the Commission. The Exchange has provided such notice.

Waiver of the 30-day operative delay would allow the Exchange to implement proposed changes in a more timely fashion. First, the proposed rule changes regarding manual signatures address operational challenges facing firms due to the ongoing public health risks stemming from the outbreak of COVID–19 and permit firms to rely on electronic signatures to satisfy the signature requirements of Exchange Rule 1904(c) and Interpretation and Policy .03, which may reduce or eliminate an operational backlog, ultimately benefiting the investing public. Moreover, the proposed rule changes do not impose any significant burden on competition because they will apply uniformly to all similarly situated members and associated persons of members. Also, as stated above, the proposed rule changes are substantively the same as changes made by FINRA. Second, waiver of the 30-day operative delay would also allow the Exchange to implement the proposed continuing education changes noted above thereby reducing the possibility of a significant regulatory gap between the FINRA and Exchange Rules. This is consistent with the protection of investors and the public interest by providing more uniform standards across the securities industry and helping to avoid confusion for members of the Exchange that are also FINRA members. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[64]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule 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–MIAX–2022–23 on the subject line.

Paper Comments:

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–MIAX–2022–23. This file number should be included on the

[60] *See supra* notes 3 and 5.

[61] 15 U.S.C. 78s(b)(3)(A)(iii).

[62] 17 CFR 240.19b–4(f)(6).

[63] 17 CFR 240.19b–4(f)(6)(iii).

[64] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–MIAX–2022–23 and should be submitted on or before July 19, 2022. For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[65]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–13704 Filed 6–27–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34621; 812–15334]

Federated Hermes Project and Trade Finance Tender Fund and Federated Investment Management Company

June 22, 2022.

AGENCY: Securities and Exchange Commission (''Commission'' or ''SEC'').

ACTION: Notice.

Notice of an application under section 6(c) of the Investment Company Act of 1940 (the ''Act'') for an exemption from sections 18(a)(2), 18(c) and 18(i) of the Act and for an order pursuant to section 17(d) of the Act and rule 17d–1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit certain registered closed-end management investment companies to issue multiple classes of shares of beneficial interest with varying sales loads and to impose asset-based distribution and/or service fees.

APPLICANTS: Federated Hermes Project and Trade Finance Tender Fund (the ''Trust''), and Federated Investment Management Company (the ''Advisor'').

FILING DATE: The application was filed on May 13, 2022.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the Commission's Secretary at *Secretarys-Office@sec.gov* and serving the relevant Applicant with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below.

Hearing requests should be received by the Commission by 5:30 p.m. on July 18, 2022, and should be accompanied by proof of service on Applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov*.

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: Peter J. Germain Esq., 1001 Liberty Avenue, Pittsburgh, Pennsylvania 15222–3779, Pablo J. Man, K&L Gates LLP, 1 Lincoln Street, Boston, Massachusetts 02111.

FOR FURTHER INFORMATION CONTACT: Asaf Barouk, Attorney-Advisor, or Terri G. Jordan, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and condition, please refer to Applicants' application, dated May 13, 2022, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field, on the SEC's EDGAR system. The SEC's EDGAR system may be searched at, at *http://www.sec.gov/edgar/searchedgar/legacy/companysearch.html.* You may also call the SEC's Public Reference Room at (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–13715 Filed 6–27–22; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-Day notice.

SUMMARY: The Small Business Administration (SBA) is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act and OMB procedures, SBA is publishing this notice to allow all interested member of the public an additional 30 days to provide comments on the proposed collection of information.

DATES: Submit comments on or before July 28, 2022.

ADDRESSES: Written comments and recommendations for this information collection request should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/*PRAMain. Find this particular information collection request by selecting ''Small Business Administration''; ''Currently Under Review,'' then select the ''Only Show ICR for Public Comment'' checkbox. This information collection can be identified by title and/or OMB Control Number.

FOR FURTHER INFORMATION CONTACT: You may obtain a copy of the information collection and supporting documents from the Agency Clearance Office at *Curtis.Rich@sba.gov;* (202) 205–7030, or from *www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: Prior to Small Business Administration (SBA) approval of subsequent loan disbursement, disaster loan borrowers are required to submit information to demonstrate that they used loan proceeds for authorized purposes only and to make certain certification regarding current financial condition and previously reported compensation paid in connection with the loan.

Solicitation of Public Comments

Comments may be submitted on (a) whether the collection of information is

[65] 17 CFR 200.30–3(a)(12).

necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

OMB Control 3245–0110

Title: Borrower's Progress Certification.

Description of Respondents: Disaster loan Borrowers.

Form Number: SBA Form 1366.

Total Estimated Annual Responses: 14,218.

Total Estimated Annual Hour Burden: 7,106.

Curtis Rich,

Agency Clearance Officer.

[FR Doc. 2022–13735 Filed 6–27–22; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-Day notice.

SUMMARY: The Small Business Administration (SBA) is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act and OMB procedures, SBA is publishing this notice to allow all interested members of the public an additional 30 days to provide comments on the proposed collection of information.

DATES: Submit comments on or before July 28, 2022.

ADDRESSES: Written comments and recommendations for this information collection request should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Small Business Administration''; ''Currently Under Review,'' then select the ''Only Show ICR for Public Comment'' checkbox. This information collection can be identified by title and/or OMB Control Number.

FOR FURTHER INFORMATION CONTACT: You may obtain a copy of the information collection and supporting documents from Curtis Rich, Agency Clearance Office, at *Curtis.Rich@sba.gov*; (202) 205–7030, or from *www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: Form 857 is used by SBA examiners to obtain information about financing provided by small business investment companies (SBICs). This information, which is collected directly from the financed small business, provides independent confirmation of information reported to SBA by SBICs, as well as additional information not reported by SBICs.

Solicitation of Public Comments: Comments may be submitted on (a) whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

OMB Control: 3245–0109.

Title: ''Request for Information Concerning Portfolio Financing.''

Description of Respondents: Small Business Investment Companies.

Estimated Number of Respondents: 857.

Estimated Annual Responses: 2,250.

Estimated Annual Hour Burden: 2,250.

Curtis Rich,

Agency Clearance Officer.

[FR Doc. 2022–13726 Filed 6–27–22; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[License No. 09/09–0496]

HCAP Partners V, L.P.; Notice Seeking Exemption Under Section 312 of the Small Business Investment Act, Conflicts of Interest

Notice is hereby given that HCAP Partners V, L.P., 3636 Nobel Dr., Suite 401, San Diego, CA 92122, a Federal Licensee under the Small Business Investment Act of 1958, as amended (''the Act''), in connection with the financing of a small concerns, has sought an exemption under Section 312 of the Act and Section 107.730, Financings which Constitute Conflict of Interest of the Small Business Administration (''SBA'') Rules and Regulations (13 CFR 107.730). HCAP Partners V, L.P. (''HCAP V'') is proposing to provide financing to Cubex LLC (''Company'') to support the Company's growth.

The proposed transaction is brought within the purview of § 107.730 of the Regulations because HCAP Partners III, L.P. (''HCAP III''), an Associate of HCAP V by virtue of Common Control as defined in § 107.50, holds a 22% of equity interest in the Company. By virtue of HCAP III's equity ownership, the Company and HCAP V are also Associates. HCAP III expects to receive $19.5 million from the proposed transaction.

Therefore, the proposed transaction requires a regulatory exemption pursuant to 13 CFR 107.730. Notice is hereby given that any interested person may submit written comments on the transaction within fifteen days of the date of this publication to Associate Administrator for Investment, U.S. Small Business Administration, 409 Third Street SW, Washington, DC 20416.

Bailey DeVries,

Associate Administrator, Office of Investment and Innovation.

[FR Doc. 2022–13781 Filed 6–27–22; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-Day notice.

SUMMARY: The Small Business Administration (SBA) is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act and OMB procedures, SBA is publishing this notice to allow all interested member of the public an additional 30 days to provide comments on the proposed collection of information.

DATES: Submit comments on or before July 28, 2022.

ADDRESSES: Written comments and recommendations for this information collection request should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Small Business Administration''; ''Currently Under Review,'' then select the ''Only Show ICR for Public Comment'' checkbox. This information collection can be identified by title and/or OMB Control Number.

FOR FURTHER INFORMATION CONTACT: You may obtain a copy of the information collection and supporting documents from Curtis Rich, Agency Clearance Office, at *Curtis.Rich@sba.gov*; (202)

205–7030, or from *www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: The Small Business Regulatory Enforcement Fairness Act of 1966, 15 U.S.C. 657(b)(2)(B), requires the SBA National Ombudsman to establish a means for SBA to receive comments on regulatory and compliance actions from small entities regarding their disagreements with a Federal Agency action. The Ombudsman uses it to obtain the agency's response, encourage a fresh look by the agency at a high level, and build a smaller business-friendly regulatory environment.

Solicitation of Public Comments: Comments may be submitted on (a) whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

OMB Control: 3245–0313.

Title: ''Federal Agency Comment Form.''

Description of Respondents: Small business entities.

Estimated Number of Respondents: 340.

Estimated Annual Responses: 340.

Estimated Annual Hour Burden: 340.

Curtis Rich,

Agency Clearance Officer.

[FR Doc. 2022–13727 Filed 6–27–22; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-Day notice.

SUMMARY: The Small Business Administration (SBA) is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act and OMB procedures, SBA is publishing this notice to allow all interested member of the public an additional 30 days to provide comments on the proposed collection of information.

DATES: Submit comments on or before July 28, 2022.

ADDRESSES: Written comments and recommendations for this information collection request should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/*PRAMain. Find this particular information collection request by selecting ''Small Business Administration''; ''Currently Under Review,'' then select the ''Only Show ICR for Public Comment'' checkbox. This information collection can be identified by title and/or OMB Control Number.

FOR FURTHER INFORMATION CONTACT: You may obtain a copy of the information collection and supporting documents from the Agency Clearance Office at *Curtis.Rich@sba.gov;* (202) 205–7030, or from *www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: A team of Quality Assurance staff at the Disaster Assistance Center (DASC) will conduct a brief telephone survey of customers to determine their satisfaction with the services received from the (DASC) and the Field Operations Centers. The result will help the Agency to improve where necessary, the delivery of critical financial assistance to disaster victims.

Solicitation of Public Comments

Comments may be submitted on (a) whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

OMB Control 3245–0370

Title: Disaster Assistance Customer Satisfaction Survey.

Description of Respondents: Disaster Customers satisfaction with service received.

Form Number: SBA Form 2313FOC, 2313CSC.

Total Estimated Annual Responses: 2,400.

Total Estimated Annual Hour Burden: 199.

Curtis Rich,

Agency Clearance Officer.

[FR Doc. 2022–13736 Filed 6–27–22; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-day notice.

SUMMARY: The Small Business Administration (SBA) is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act and OMB procedures, SBA is publishing this notice to allow all interested member of the public an additional 30 days to provide comments on the proposed collection of information.

DATES: Submit comments on or before July 28, 2022.

ADDRESSES: Written comments and recommendations for this information collection request should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Small Business Administration''; ''Currently Under Review,'' then select the ''Only Show ICR for Public Comment'' checkbox. This information collection can be identified by title and/or OMB Control Number.

FOR FURTHER INFORMATION CONTACT: You may obtain a copy of the information collection and supporting documents from Curtis Rich, Agency Clearance Office, at *Curtis.Rich@sba.gov*; (202) 205–7030, or from *www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with regulations and policy, the Small Business Development Centers (SBDCs) must provide SBA semi-annual financial and programmatic reports outlining expenditures and accomplishments. The information collected will be used to monitor the progress of the program. The Office of Entrepreneurial Development made minor adjustments to the form in number (3), under the heading EXPENSE CATEGORY to align with the SF 424 as follows:

1. Travel is moved from the fifth line to the third line.
2. Equipment is moved from the sixth line to the fourth line.
3. Supplies is moved from the seventh line to the fifth line.
4. Contractual is added as the sixth line.
5. Consultants is moved from the third line to the seventh line.

The remainder of the form stays the same.

Solicitation of Public Comments

Comments may be submitted on (a) whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the

burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

OMB Control 3245–0169

Title: ''Federal Cash Transaction Report; Financial Status Report Program Income Report Narrative Program Report''.

Description of Respondents: SBDC Program Stakeholders, including State Directors.

Estimated Number of Respondents: 126.

Estimated Annual Responses: 126.

Estimated Annual Hour Burden: 7,308.

Curtis Rich,

Agency Clearance Officer.

[FR Doc. 2022–13733 Filed 6–27–22; 8:45 am]

BILLING CODE 8026–09–P

DEPARTMENT OF STATE

[Public Notice 11771]

30-Day Notice of Proposed Information Collection: Statement of Political Contributions, Fees, and Commissions Relating to Sales of Defense Articles and Defense Services

ACTION: Notice of request for public comment and submission to the Office of Management and Budget of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments up to July 28, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument, and supporting documents, to Andrea Battista, who may be reached at *BattistaAL@state.gov* or 202–663–3136.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Statement of Political Contributions, Fees, and Commissions Relating to Sales of Defense Articles and Defense Services.
- *OMB Control Number:* 1405–0025.
- *Type of Request:* Extension.
- *Originating Office:* Directorate of Defense Trade Controls (DDTC).
- *Form Number:* No Form.
- *Respondents:* Persons requesting a license or other approval for the export, reexport, or retransfer of USML-regulated defense articles or defense services valued in an amount of $500,000 or more that are being sold commercially to or for the use of the armed forces of a foreign country or international organization or persons who enter into a contract with the Department of Defense for the sale of defense articles or defense services valued in an amount of $500,000 or more under section 22 of the AECA.
- *Estimated Number of Respondents:* 57.
- *Estimated Number of Responses:* 450.
- *Average Time per Response:* 60 minutes.
- *Total Estimated Burden Time:* 450 hours.
- *Frequency:* On occasion.
- *Obligation to Respond:* Mandatory.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- 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.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

DDTC regulates the export and temporary import of defense articles and defense services enumerated on the U.S. Munitions List (USML) in accordance with the Arms Export Control Act (AECA) (22 U.S.C. 2751 *et seq.*) and the International Traffic in Arms Regulations (ITAR) (22 CFR parts 120–130). In accordance with section 39 of the AECA, the Secretary of State must require, in part, adequate and timely reporting of political contributions, gifts, commissions and fees paid, or offered or agreed to be paid in connection with the sales of defense articles or defense services licensed or approved under AECA sections 22 and 38. Pursuant to ITAR § 130.9(a), any person applying for a license or approval required under section 38 of the AECA for sale to the armed forces of a foreign country or international organization valued at $500,000 or more must inform DDTC, and provide certain specified information, when they have paid, offered to, or agreed to pay, (1) political contributions in an aggregate amount of $5,000 or greater; or (2) fees or commissions in an aggregate amount equaling or exceeding $100,000. Similarly, ITAR § 130.9(b) requires any person who enters into a contract with the Department of Defense under section 22 of the AECA, valued at $500,000 or more, to inform DDTC and provide the specified information, when they or their vendors, have paid, or offered or agreed to pay, in respect to any sale (1) political contributions in an aggregate amount of $5,000 or greater; or (2) fees or commissions in an aggregate amount equaling or exceeding $100,000. Applicants are also required to collect information pursuant to Sections 130.12 and 130.13 prior to submitting their report to DDTC.

Methodology

Applicants will submit information as attachments to relevant license applications or requests for other approval.

Michael F. Miller,

Deputy Assistant Secretary, Directorate of Defense Trade Controls, Department of State.

[FR Doc. 2022–13788 Filed 6–27–22; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2016–0420]

Commercial Driver's License (CDL): New Prime, Inc. (Prime); Application for Exemption Renewal

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of provisional renewal of exemption; request for comments.

SUMMARY: FMCSA announces its decision to provisionally renew a New Prime, Inc., (Prime) exemption from the provisions that require a commercial learner's permit (CLP) holder to be accompanied by a commercial driver's license (CDL) holder with the proper CDL class and endorsements seated in the front seat of the vehicle while the CLP holder performs behind-the-wheel training on public roads or highways. The exemption allows a CLP holder who has passed the skills test but not yet received the CDL document to drive a Prime commercial motor vehicle (CMV) accompanied by a CDL holder who is not necessarily in the passenger seat, provided the driver has documentation of passing the skills test. The exemption renewal is for 5 years.

DATES: *This renewed exemption is effective June 28, 2022 and expires on June 27, 2027.* Comments must be received on or before July 28, 2022.

ADDRESSES: You may submit comments identified by Federal Docket Management System (FDMS) Number FMCSA–2016–0420 by any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* See the Public Participation and Request for Comments section below for further information.
- *Mail:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, between 9 a.m. and 5 p.m. E.T., Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

Each submission must include the Agency name and the docket number (FMCSA–2016–0420) for this notice. Note that DOT posts all comments received without change to *www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to *www.regulations.gov* at any time or visit Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

Privacy Act: In accordance with 49 U.S.C. 31315(b), DOT solicits comments from the public to better inform its exemption process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice DOT/ALL 14 –FDMS, which can be reviewed at *https://www.transportation.gov/privacy.*

FOR FURTHER INFORMATION CONTACT: Ms. Bernadette Walker, Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards, FMCSA, at (202) 385–2415 or by email at *MCPSD@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Dockets Operations at (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2016–0420), indicate the specific section of this document to which the comment applies, and provide a reason for suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to *www.regulations.gov* and put the docket number (''FMCSA–2016–0420'') in the ''Keyword'' box, and click ''Search.'' When the new screen appears, click on the ''Comment Now!'' button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. FMCSA will consider all comments and material received during the comment period.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b)(2) and 49 CFR 381.300(b) to renew an exemption from the Federal Motor Carrier Safety Regulations for a 5-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption.'' Prime has requested a five-year extension of the current exemption in Docket No. FMCSA–2016–0420.

III. Background

Current Regulatory Requirements

FMCSA's CDL regulations provide minimum training conditions for behind-the-wheel training of a CLP holder in 49 CFR 383.25. Section 383.25(a)(1) requires that a CLP holder must at all times be accompanied by a CDL holder with the proper CDL class and endorsements. The CDL holder must be seated in the front seat of the vehicle while the CLP holder performs behind-the-wheel training on public roads or highways.

Application for Renewal of Exemption

FMCSA published notice of Prime's initial application for exemption from 49 CFR 383.25(a)(1) to this docket on December 20, 2016 (81 FR 92947). That notice described the nature of Prime's operations. FMCSA published a notice granting Prime's exemption request on June 27, 2017 (82 FR 29143), which expires on June 27, 2022. FMCSA found that Prime would likely achieve a level of safety that was equivalent to, or greater than, the level of safety that would be obtained by complying with the regulation because CLP holders who have passed the CDL skills test are qualified and eligible immediately to obtain a CDL from their State of domicile, and then to start driving without supervision.

Prime requests a renewal of the exemption for a 10-year period. By statute, FMCSA may grant the renewal for no longer than 5 years (49 U.S.C. 31315(b)(2)).

IV. Equivalent Level of Safety

FMCSA determined in 2017 that Prime drivers would likely achieve a

level of safety equivalent to, or greater than, the level of safety achieved without the exemption. FMCSA noted in its June 27, 2017, notice that CLP holders who have passed the CDL skills test are qualified and eligible to obtain a CDL. If those CLP holders obtained their CLPs and training in their State of domicile, they could immediately receive their CDL at the State driver licensing agency and begin driving a CMV without any on-board supervision.

In its March 9, 2022, application for renewal, Prime states that it has not discovered any safety issues while operating under the exemption and that it will continue to monitor its safety data. Prime further states that its ''lead seat'' trainers commonly own their trucks and are therefore interested in ensuring that the CLP holder operates the CMV safely. In addition, Prime states that once its CLP holders have passed the CDL skills test, they continue into their second phase of training, in which they typically log more than 30,000 miles before becoming a solo driver.

FMCSA is unaware of any evidence of a degradation of safety attributable to the current exemption for Prime drivers. There is no indication of an adverse impact on safety while operating under the terms and conditions specified in the initial exemption or exemption renewal. Furthermore, on two previous occasions the Agency granted a similar exemption, to CRST Expedited [81 FR 65696, September 23, 2016] and to C.R. England [80 FR 33329, June 11, 2015].

FMCSA concludes that provisionally extending the exemption granted on June 27, 2017, for another five years, under the terms and conditions listed below, will likely achieve a level of safety that is equivalent to, or greater than, the level of safety achieved without the exemption.

V. Exemption Decision

A. Grant of Exemption

FMCSA provisionally renews the exemption for a period of five years subject to the terms and conditions of this decision and the absence of public comments that would cause the Agency to terminate the exemption under Sec. V.F. below. The exemption from the requirements of 49 CFR 383.25(a)(1), is otherwise effective June 28, 2022, through June 27, 2027, 11:59 p.m. local time, unless renewed or rescinded.

B. Applicability of Exemption

The exemption excuses Prime from the requirement that a driver accompanying a CLP holder must always be physically present in the front seat of a CMV, on the condition that the CLP holder has successfully passed an approved CDL skills test.

C. Terms and Conditions

When operating under this exemption, Prime and its drivers are subject to the following terms and conditions:

(1) Prime and its drivers must comply with all other applicable Federal Motor Carrier Safety Regulations (49 CFR part 350–399);

(2) The drivers must be in possession of a valid State driver's license, CLP with the required endorsements, and documentation that they have passed the CDL skills test;

(3) The drivers must not be subject to any OOS order or suspension of driving privileges; and

(4) The drivers must be able to provide this exemption document to enforcement officials.

D. Preemption

In accordance with 49 U.S.C. 31315(d), as implemented by 49 CFR 381.600, during the period this exemption is in effect, no State shall enforce any law or regulation that conflicts with or is inconsistent with this exemption with respect to a firm or person operating under the exemption. States may, but are not required to, adopt the same exemption with respect to operations in intrastate commerce.

E. Notification to FMCSA

Prime must notify FMCSA within 5 business days of any crash (as defined in 49 CFR 390.5) involving any of its CMVs operating under the terms of this exemption. The notification must include the following information:

(a) Name of the exemption: ''Prime'';

(b) Date of the crash;

(c) City or town, and State, in which the crash occurred, or closest to the crash scene;

(d) Driver's name and license number;

(e) Vehicle number and State license number;

(f) Number of individuals suffering physical injury;

(g) Number of fatalities;

(h) The police-reported cause of the crash;

(i) Whether the driver was cited for violation of any traffic laws, motor carrier safety regulations; and

(j) The driver's total driving time and total on-duty time prior to the crash.

Reports filed under this provision shall be emailed to *MCPSD@DOT.GOV.*

F. Termination

FMCSA does not believe the drivers covered by this exemption will experience any deterioration of their safety record. The exemption will be rescinded if: (1) Prime and drivers operating under the exemption fail to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objects of 49 U.S.C. 31136(e) and 31315.

VI. Request for Comments

In accordance with 49 U.S.C. 31315(b), FMCSA requests public comment from all interested persons on Prime, Inc.'s application for an exemption from the requirement in 49 CFR 383.25(a)(1) that would allow CLP holders who have successfully passed a CDL skills test and are eligible to receive, but have not yet obtained, a CDL to drive a CMV without a CDL holder in the front passenger seat. All comments received before the close of business on the comment closing date indicated at the beginning of this notice will be considered and will be available for examination in the docket at the location listed under the Addresses section of this notice. Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable. In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should continue to examine the public docket for new material.

Robin Hutcheson,

Deputy Administrator.

[FR Doc. 2022–13709 Filed 6–27–22; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2010–0031]

Long Island Rail Road's Request To Amend Its Positive Train Control Safety Plan and Positive Train Control System

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of availability and request for comments.

SUMMARY: This document provides the public with notice that, on June 9, 2022, Long Island Rail Road (LIRR) submitted a request for amendment (RFA) to its FRA-approved Positive Train Control

Safety Plan (PTCSP). As this RFA may involve a request for FRA's approval of proposed material modifications to an FRA-certified positive train control (PTC) system, FRA is publishing this notice and inviting public comment on the railroad's RFA to its PTCSP.

DATES: FRA will consider comments received by July 18, 2022. FRA may consider comments received after that date to the extent practicable and without delaying implementation of valuable or necessary modifications to a PTC system.

ADDRESSES: *Comments:* Comments may be submitted by going to *https://www.regulations.gov* and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name and the applicable docket number. The relevant PTC docket number for this host railroad is Docket No. FRA–2010–0031. For convenience, all active PTC dockets are hyperlinked on FRA's website at *https://railroads.dot.gov/train-control/ptc/ptc-annual-and-quarterly-reports.* All comments received will be posted without change to *https://www.regulations.gov;* this includes any personal information.

FOR FURTHER INFORMATION CONTACT: Gabe Neal, Staff Director, Signal, Train Control, and Crossings Division, telephone: 816–516–7168, email: *Gabe.Neal@dot.gov.*

SUPPLEMENTARY INFORMATION: In general, Title 49 United States Code (U.S.C.) Section 20157(h) requires FRA to certify that a host railroad's PTC system complies with Title 49 Code of Federal Regulations (CFR) part 236, subpart I, before the technology may be operated in revenue service. Before making certain changes to an FRA-certified PTC system or the associated FRA-approved PTCSP, a host railroad must submit, and obtain FRA's approval of, an RFA to its PTCSP under 49 CFR 236.1021.

Under 49 CFR 236.1021(e), FRA's regulations provide that FRA will publish a notice in the **Federal Register** and invite public comment in accordance with 49 CFR part 211, if an RFA includes a request for approval of a material modification of a signal and train control system. Accordingly, this notice informs the public that, on June 9, 2022, LIRR submitted an RFA to its PTCSP for its Advanced Civil Speed Enforcement System II (ACSES II) and that RFA is available in Docket No. FRA–2010–0031.

Interested parties are invited to comment on LIRR's RFA to its PTCSP by submitting written comments or data. During FRA's review of this railroad's RFA, FRA will consider any comments or data submitted within the timeline specified in this notice and to the extent practicable, without delaying implementation of valuable or necessary modifications to a PTC system. *See* 49 CFR 236.1021; *see also* 49 CFR 236.1011(e). Under 49 CFR 236.1021, FRA maintains the authority to approve, approve with conditions, or deny a railroad's RFA to its PTCSP at FRA's sole discretion.

Privacy Act Notice

In accordance with 49 CFR 211.3, FRA solicits comments from the public to better inform its decisions. DOT posts these comments, without edit, including any personal information the commenter provides, to *https://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See *https://www.regulations.gov/privacy-notice* for the privacy notice of regulations.gov. To facilitate comment tracking, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. If you wish to provide comments containing proprietary or confidential information, please contact FRA for alternate submission instructions.

Issued in Washington, DC.

Carolyn R. Hayward-Williams,

Director, Office of Railroad Systems and Technology.

[FR Doc. 2022–13703 Filed 6–27–22; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2022–0035]

Guidance on Development and Implementation of Railroad Capital Projects

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of proposed guidance.

SUMMARY: FRA proposes guidance on the development and implementation of railroad capital projects that are funded, in whole or in part, by FRA. FRA seeks comment from the public on the content and application of the proposed guidance (''guidance''), which is available for review at *https://regulations.gov* under docket number FRA–2022–0035.

DATES: Comments are encouraged and will be accepted until August 12, 2022.

ADDRESSES: Comments should refer to docket number FRA–2022–0035 and be submitted at *https://regulations.gov.* Search by using the docket number and follow the instructions for submitting comments. All submissions must include the agency name and docket number FRA–2022–0035.

FOR FURTHER INFORMATION CONTACT: For further information, please contact David Valenstein, Senior Advisor, Office of Infrastructure Investment, by email: *david.valenstein@dot.gov* or by telephone: 202–493–6368.

SUPPLEMENTARY INFORMATION: FRA has identified the time-sensitive need to establish clear practices and procedures for the development and implementation of railroad capital projects through the issuance of agency guidance. Over the next five years, the Infrastructure Investment and Jobs Act (IIJA) (Pub. L. 117–58, also known as the ''Bipartisan Infrastructure Law'') will provide unprecedented Federal funding for rail improvement projects in America. FRA intends for its final guidance to assist project sponsors in developing effective capital projects and to enhance the management of capital projects to meet budgets and schedules.

The audience of the guidance includes project sponsors and partners, as well as the wide range of professionals who contribute to the planning, development, and implementation of railroad capital projects. The guidance: (1) defines the stages in the railroad capital project lifecycle and project development process from inception to operation; (2) describes the project management tools, processes, and documentation that FRA may require when providing grants that fund the development or implementation of a railroad capital project; (3) differentiates between Non-Major projects and Major projects by defining a ''Major Project'' as a railroad capital project with an estimated total project cost equal to or greater than $300 million and with at least $100 million in total Federal assistance.

FRA intends to strongly encourage project sponsors to follow the guidance when developing, implementing, and managing railroad capital projects. FRA may use the guidance to inform its grant application reviews and decisions in accordance with a process described in a notice of funding opportunity for the relevant grant program, and may require compliance with the guidance as part of grant agreements funding railroad capital projects in accordance with 2 CFR parts 200 and 1201. The practices contained in the guidance draw from FRA's experience and from established

programs of other DOT operating administrations that have enhanced the delivery of major highway and transit projects.

FRA is seeking feedback on the following items:

- Definitions established in the guidance, particularly the definitions of a Major Project and a Project Sponsor. FRA is proposing a Major Project definition that is similar to the definition used by the Federal Transit Administration (FTA). FRA's definition of Project Sponsor accounts for the range of public and private applicants eligible for FRA grant programs.
- The potential application of this guidance to railroad projects receiving financing or funding under the credit and grant programs administered by the DOT.
- Project Lifecycle Stages, including the FRA Project Lifecycle Model and terminology in relationship to past FRA programs and to the project lifecycle models of the FTA and Federal Highway Administration (FHWA). FRA proposes a model consisting of six stages: (1) Systems Planning, (2) Project Planning, (3) Project Development, (4) Final Design, (5) Construction, and (6) Operation. FRA proposes these terms for their clarity over other terminology such as FRA's past term PE/NEPA for the third stage. FHWA has described a normal lifecycle for highway projects following five phases: (1) planning, (2) preliminary design and environmental review, (3) final design and right-of-way acquisition, (4) construction, and (5) operation.[1] FTA follows another similar model for the Capital Investment Grant Program which requires three steps after completion of planning: (1) Project Development, (2) Engineering, and (3) Construction.
- The completion measures for the Project Planning, Project Development, Final Design, and Construction lifecycle stages, particularly the milestone activities relating to planning, engineering/design, environmental review, and project management tools.
- The four project management tools featured and how they are described, including the differences between Non-Major and Major projects.
- The lifecycle progression of project delivery planning and implementation including consideration of public-private partnerships and innovative procurements. The lifecycle model describes initial Project Sponsor consideration of delivery for Major Projects during the Project Planning stage and progressive refinement in later stages.
- Any other suggestions for enhancing the guidance.

Privacy Act

FRA is soliciting comments from the public to better inform its guidance process. FRA posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.* In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

Issued in Washington, DC.

Paul Nissenbaum,

Associate Administrator, Office of Railroad Policy and Development.

[FR Doc. 2022–13747 Filed 6–27–22; 8:45 am]

BILLING CODE 4910–06–P

[1] *https://highways.dot.gov/public-roads/julyaugust-2004/life-cycle-continuum,* Accessed April 21, 2022.

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2020–0073]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Request for Comment; Survey on Driver Awareness of Motorcycles

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for comments on a new information collection.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (PRA), this notice announces that the Information Collection Request (ICR) abstracted below will be submitted to the Office of Management and Budget (OMB) for review and approval. The ICR describes the nature of the information collection and its expected burden. This document describes a new collection of information for which NHTSA intends to seek OMB approval. The Survey on Driver Awareness of Motorcycles is a one-time voluntary survey regarding motorists' knowledge, attitudes, and awareness of safe-driving behaviors towards motorcycles. A **Federal Register** notice with a 60-day comment period soliciting public comments on the following information collection was published on April 7, 2022. NHTSA received seven comments. The National Association of Mutual Insurance Companies submitted a letter of support for the proposed information collection, as did two individuals. The other four comments were either neutral, implicitly supportive, or not directly relevant to the proposed information collection, as described below.

DATES: Comments must be submitted on or before August 29, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection, including suggestions for reducing burden, should be submitted to the Office of Management and Budget at *www.reginfo.gov/public/do/PRAMain.* To find this particular information collection, select ''Currently under Review—Open for Public Comment'' or use the search function. Comments may also be sent by mail to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503, Attention: Desk Officer for Department of Transportation, National Highway Traffic Safety Administration, or by email at *oira_submission@omb.eop.gov,* or fax: 202–395–5806.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact Kathryn Wochinger, Ph.D., Office of Behavioral Safety Research (NPD–310), (202) 366–4300, *kathryn.wochinger@dot.gov,* National Highway Traffic Safety Administration, W46–487, 1200 New Jersey Avenue SE, Washington, DC 20590.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501 *et seq.*) a Federal agency must receive approval from the Office of Management and Budget (OMB) before it collects certain information from the public and a person is not required to respond to a collection of information by a Federal agency unless the collection displays a valid OMB control number. In compliance with these requirements, this notice announces that the following information collection request will be submitted to OMB.

A **Federal Register** notice with a 60-day comment period soliciting public comments on the following information collection was published on April 7, 2022 (**Federal Register**/Vol. 87, No. 67/pp. 20501–20504). NHTSA received six

comments from individuals and one letter from the National Association of Mutual Insurance Companies expressing support for the proposed information collection. John Banta and John Tramburg provided comments supportive of the information collection. A third individual (John Herlihy) commented that ''. . . the most dangerous part about [riding a motorcycle] is other vehicle operators.'' A fourth anonymous post was that ''. . . many riders are most concerned about the use of additional ethenol [sic] in our gasoline as a method to increase the supply of gasoline and control price points,'' but the issue of gasoline is not addressed in the proposed information collection. A fifth comment submitted by Andy Kelly was about training of automobile drivers and motorcycle operators in the Commonwealth of Pennsylvania. The sixth comment from John Chico Bethea was that ''. . . the greatest danger to a modern motorcyclist are [sic] the other motor vehicle (cars, trucks, SUVs) drivers on their cell phones.'' We appreciate the letter of support from the National Association of Mutual Insurance Companies and the comments from each individual and thank them for their input.

Title: Survey on Driver Awareness of Motorcycles.

OMB Control Number: New.

Form Numbers: NHTSA Forms 1577, 1578, 1579, 1580, 1581, 1582, 1583, and 1588.

Type of Request: Approval of a new information collection.

Type of Review Requested: Regular.

Requested Expiration Date of Approval: 3 years from date of approval.

Summary of the Collection of Information: NHTSA is seeking approval to collect information from two samples of randomly selected adults who are aged 18 years or older and have driven a motor vehicle at least once in the past three months for a new one-time voluntary survey to report their knowledge, attitudes, and awareness of safe-driving behaviors towards motorcycles. One sample consists of adult drivers residing in Florida, and the other sample consists of adult drivers residing in Pennsylvania. Surveys would be conducted with respondents using an address-based sampling design that encourages respondents to complete the survey online. NHTSA will contact a total of 33,460 to achieve a target of at least 2,486 complete voluntary responses consisting of 1,243 completed instruments from the Florida sample and 1,243 completed instruments from the Pennsylvania sample. The large geographic and demographic sizes of Florida and Pennsylvania allow for complex driving environments in which motorcycles and passenger vehicles operate in a range of traffic conditions. An Institutional Review Board (IRB) determined that this proposed information collection is exempt from IRB oversight. NHTSA will summarize the results of the collection using aggregate statistics in a final report to be distributed to NHTSA program and regional offices, State Highway Safety Offices, and other traffic safety and motorcycle safety stakeholders. This collection supports NHTSA's mission by obtaining information needed for the development of traffic safety countermeasures, particularly in the areas of communications and outreach, for the purpose of reducing fatalities, injuries, and crashes associated with multi-vehicle motorcycle crashes.

Description of the Need for the Information and Proposed Use of the Information: NHTSA was established by the Highway Safety Act of 1970 to reduce deaths, injuries, and economic losses resulting from motor vehicle crashes on the Nation's highways. To further its mission, NHTSA is authorized to conduct research as a foundation for the development of traffic safety programs. Title 23, United States Code, Section 403, gives the Secretary of Transportation (NHTSA by delegation) authorization to use funds appropriated to conduct research and development activities, including demonstration projects and the collection and analysis of highway and motor vehicle safety data and related information, with respect to all aspects of highway and traffic safety systems and conditions relating to vehicle, highway, driver, passenger, motorcyclist, bicyclist, and pedestrian characteristics; accident causation and investigations; and human behavioral factors and their effect on highway and traffic safety. Motorcycle safety is a behavioral area for which NHTSA has developed programs to meet its injury reduction goals. Motorcycle safety is an increasing safety concern in highway transportation. For example, per vehicle miles traveled in 2019, motorcyclist fatalities occurred nearly 29 times more frequently than passenger car occupant fatalities in traffic crashes, and an estimated 84,000 motorcyclists were injured in 2019, which is a 2-percent increase from 82,000 motorcyclists injured in 2018; the most harmful event for 55 percent of the 5,114 motorcycles involved in fatal crashes in 2019 was a collision with another motor vehicle; and in two-vehicle crashes, 76 percent of the motorcycles involved in fatal crashes were struck in the front. Thus, strategies for improving motorcycle safety include addressing other motorists' perceptions and awareness of motorcycles.

This collection supports NHTSA's efforts to increase motorcyclist safety by examining factors related to the interactions between motorcycles and other motorists and their vehicles. The information from this collection will assist NHTSA in (a) assessing the extent and limitations of motorist knowledge of safe behaviors toward motorcycles, and (b) identifying the issues to emphasize in traffic safety campaigns and driver education. The collected information will help identify the beliefs, attitudes, and perceptions underlying driving behaviors towards motorcycles and inform the development of countermeasures to improve the safety of interactions between motor vehicles, specifically, motorcycles, and other vehicle types (primarily passenger cars and Sport Utility Vehicles (SUVs)).

The survey data will be used to assist NHTSA in its ongoing responsibilities for: (a) planning and designing research and program activities to improve motorcycle safety; (b) providing support to groups involved in developing and implementing motorcycle safety outreach programs and driver safety campaigns; and (c) identifying areas in driver awareness and knowledge that need attention. NHTSA will use the information to produce a technical report that presents the results of the study. The technical report will provide aggregate (summary) statistics and tables as well as the results of statistical analysis of the information, but it will not include any personally identifiable information. The project data will serve as a resource for NHTSA and stakeholders to identify gaps in knowledge among the driving public. The technical report will be shared with State highway offices, local governments, and those who develop traffic safety communications that aim to improve motorcycle safety.

Affected Public: Participants will be U.S. adults (18 years and older) who reside in Florida or Pennsylvania and who have driven a motor vehicle (car, van, SUV, or pickup truck) at least once in the past three months. Businesses are ineligible for the sample and would not be surveyed.

Estimated Number of Respondents: 2,486.

Participation in this study is voluntary. The estimated respondents consist of 1,243 in the Florida sample and 1,243 in the Pennsylvania sample. The project will invite 33,460 people to

participate using address data from the most recent U.S. Postal Service computerized Delivery Sequence File of residential addresses. No more than one respondent will be selected per household.

Frequency of Collection: The study will be conducted one time during the three-year period for which NHTSA is requesting approval and there will be no recurrence.

Estimated Total Annual Burden Hours: NHTSA estimates the total burden of this information collection by estimating the burden to those who NHTSA contacts who respond and are eligible for participation (eligible respondents that take the survey) and those contacted that choose not to take the survey (non-responders) or are not eligible to participate. The estimated time to contact 33,460 potential participants (participants and non-responders) for the survey is one minute per person per contact attempt. Contact attempts will be made in five waves with fewer potential participants contacted in each subsequent wave. Potential participants will receive an initial postcard informing them of the project and inviting participation. The first contact is a postcard introducing the project and inviting participation. The second contact is an invitation letter with instructions for completing the survey online (as the methodology follows a ''push-to-web'' design to provide incentive to complete the survey online). The third contact is a reminder postcard. The fourth is a letter with a paper questionnaire and the fifth is a final reminder postcard. The sixth and final wave is a ''thank you'' letter that will include the contingent incentive to respondents who have provided a completed response. NHTSA estimates that 2,486 people will respond to the survey request. The estimated time to contact (1 minute) and complete the survey (14 minutes) is 15 minutes per person. The total burden estimated for this information collection is 3,289 hours. Table 1 provides a description for each of the forms used in the survey protocol as well as their mailing wave. Details of the burden hours for each wave in the survey are included in Table 2. When rounded up to the nearest whole hour for each data collection effort, the total estimated annual burden is 3,289 hours for the project activities.

TABLE 1—NHTSA FORM NUMBER, DESCRIPTION, AND MAILING WAVE

NHTSA form No.	Description	Mailing wave
1577	Initial Postcard—serves as a notice of selection, explains survey rationale	1
1578	Invitation Letter—provides instructions and hyperlink to the online survey and includes the $1 non-contingent incentive.	2
1579	Reminder Postcard #1—the first reminder, includes instructions and hyperlink to the online survey	3
1580	Reminder Letter #1—the second reminder with the paper survey, prepaid return envelope, PIN, and hyperlink to the online survey.	4
1581	Reminder Postcard #2—last reminder, includes hyperlink to the online survey	5
1582	Questionnaire—the online version, provided on a secure website	2, 3, 4, 5
1583	Questionnaire—the paper version, for responders not using the online questionnaire	4
1588	Thank You Letter—includes the contingent incentive	6

Table 2 shows the estimated burden for each contact (wave) by participation type (non-respondent, eligible, and ineligible). In the first wave, 33,460 potential respondents are expected to spend 1 minute each reading the postcard, resulting in an estimated burden of 558 hours. This calculation is applied for each subsequent wave, as detailed in Table 2.

TABLE 2—ESTIMATED TOTAL BURDEN FOR DATA COLLECTION

Mailing wave (Form No.)	Number of contacts	Participant type	Estimated burden per sample unit (in minutes)	Frequency of burden	Number of sample units	Burden hours	Total burden hours
Wave 1 NHTSA Form 1577	33,460	Contacted potential participant	1	1	33,460	558	558
Wave 2 NHTSA Form 1578	33,460	Non-respondent	1	1	31,787	530	870
		Ineligible respondent	1	1	335	6	
		Eligible respondent	15	1	1,338	334	
Wave 3 NHTSA Form 1579	31,787	Non-respondent	1	1	30,833	514	708
		Ineligible respondent	1	1	191	3	
		Eligible respondent	15	1	763	191	
Wave 4 NHTSA Form 1580	30,833	Non-respondent	1	1	30,524	509	572
		Ineligible respondent	1	1	62	1	
		Eligible respondent	15	1	247	62	
Wave 5 NHTSA Form 1581	30,524	Non-respondent	1	1	30,351	506	541
		Ineligible respondent	1	1	35	1	
		Eligible respondent	15	1	138	34	
Wave 6 NHTSA Form 1588	2,486	Completed responders	1	1	2,486	41	41
Total							3,289

Table 3 provides total burden hours associated with each NHTSA form. For example, 2,486 anticipated responders who provide completed questionnaires (NHTSA Forms 1582 and 1583) are expected to spend 14 minutes each, resulting in an estimated burden of 580 hours.

TABLE 3—ESTIMATED TOTAL BURDEN BY NHTSA FORM FOR THE DATA COLLECTION

Information collection	Number of responses	Burden per response (minutes)	Burden per respondent (minutes)	Total burden hours
Questionnaire—NHTSA Forms 1582 and 1583	2,486	14	14	580
Initial Postcard—NHTSA Form 1577	33,460	1	1	558
Invitation Letter—NHTSA Form 1578	33,460	1	1	558
Postcard Reminder—NHTSA Form 1579	31,787	1	1	530
Reminder Letter—NHTSA Form 1580	30,833	1	1	514
Final Postcard Reminder—NHTSA Form 1581	30,524	1	1	508
Thank You Letter—NHTSA Form 1588	2,486	1	1	41
Total				3,289

Estimated Total Annual Burden Cost: NHTSA estimates that there are no costs to respondents beyond the time spent participating in the study.

Public Comments Invited: You are asked to comment on any aspects of this information collection, including (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the Department's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; 49 CFR 1.49; and DOT Order 1351.29.

Nanda Narayanan Srinivasan,

Associate Administrator, Research and Program Development.

[FR Doc. 2022–13721 Filed 6–27–22; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary of Transportation

[Docket No. DOT–OST–2020–0105]

Approval of and Antitrust Immunity for Alliance Agreements Under 49 U.S.C. 41308 and 41309

AGENCY: Office of the Secretary of Transportation (OST), Department of Transportation (DOT).

ACTION: Notice of order to show cause.

SUMMARY: The United States Department of Transportation has issued an Order to Show Cause tentatively approving and granting antitrust immunity (''ATI'') to a proposed alliance between Delta Air Lines and LATAM Airlines, subject to certain conditions. Interested stakeholders are invited to submit comments on the tentative decision.

DATES: Objections or comments to the Department's tentative findings and conclusions shall be due no later than 14 calendar days from the service date of the Order (*i.e.,* July 7, 2022), and answers to objections shall be due no later than seven (7) business days thereafter (*i.e.,* July 18, 2022). In the event that no objections are filed, all further procedural steps shall be deemed waived, and we may enter an order making final our tentative findings and conclusions.

ADDRESSES: You may send comments, identified by docket number DOT–OST–2020–0105, via the Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for sending comments. In addition, comments must be properly served on all interested parties in accordance with the Department's procedural regulations (14 CFR part 302).

FOR FURTHER INFORMATION CONTACT: Jason Horner, Transportation Industry Analyst, Office of Aviation Analysis, 1200 New Jersey Ave SE, Washington, DC 20590; telephone (202) 366–5903; email *jason.horner@dot.gov.*

SUPPLEMENTARY INFORMATION: On June 23, 2022, the Department issued an Order to Show Cause (Order 2022–6–15, ''Show Cause Order'') tentatively approving and granting ATI to a proposed alliance between Delta Air Lines and LATAM Airlines, subject to certain conditions. If approved, Delta and LATAM will jointly plan, price, and share revenues and costs under a joint venture (JV) covering routes between the United States and Canada on one end, and Brazil, Chile, Colombia, Paraguay, Peru, and Uruguay on the other end.

The Show Cause Order has been posted in docket DOT–OST–2020–0105 at *www.regulations.gov.* We direct all interested persons to show cause why we should not issue an order making final our tentative findings and conclusions discussed herein. Objections or comments to our tentative findings and conclusions shall be due no later than 14 calendar days from the service date of the Order (*i.e.,* July 7, 2022), and answers to objections shall be due no later than seven (7) business days thereafter (*i.e.,* July 18, 2022). In the event that no objections are filed, all further procedural steps shall be deemed waived, and we may enter an order making final our tentative findings and conclusions.

(Authority: 14 CFR part 303.43)

Dated: June 23, 2022.

Carol Annette Petsonk,

Assistant Secretary for Aviation and International Affairs, U.S. Department of Transportation.

[FR Doc. 2022–13786 Filed 6–27–22; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Submission for OMB Review; Interagency Guidance on Asset Securitization Activities

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on a continuing information collection as required by the Paperwork Reduction Act of 1995 (PRA). In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and respondents are not required to respond to, an information collection unless it

displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning renewal of its information collection titled ''Interagency Guidance on Asset Securitization Activities.'' The OCC also is giving notice that it has sent the collection to OMB for review.

DATES: Comments must be submitted on or before July 28, 2022.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email: prainfo@occ.treas.gov.*
- *Mail:* Chief Counsel's Office, Attention: Comment Processing, 1557–0217, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Fax:* (571) 465–4326.

Instructions: You must include ''OCC'' as the agency name and ''1557–0217'' in your comment. In general, the OCC will publish comments on *www.reginfo.gov* without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Written comments and recommendations for the proposed information collection should also 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.

On March 10, 2022, the OCC published a 60-day notice for this information collection, 87 FR 13792. You may review comments and other related materials that pertain to this information collection following the close of the 30-day comment period for this notice by the method set forth in the next bullet.

- *Viewing Comments Electronically:* Go to *www.reginfo.gov.* Hover over the ''Information Collection Review'' tab and click on ''Information Collection Review'' drop-down menu. From the ''Currently under Review'' drop-down menu, select ''Department of Treasury'' and then click ''submit.'' This information collection can be located by searching by OMB control number ''1557–0217'' or ''Interagency Guidance on Asset Securitization Activities.'' Upon finding the appropriate information collection, click on the related ''ICR Reference Number.'' On the next screen, select ''View Supporting Statement and Other Documents'' and then click on the link to any comment listed at the bottom of the screen.
- For assistance in navigating *www.reginfo.gov,* please contact the Regulatory Information Service Center at (202) 482–7340.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, OCC Clearance Officer, (202) 649–5490, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from OMB for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The OCC asks that OMB extend its approval of the collection in this notice.

Title: Interagency Guidance on Asset Securitization Activities.

OMB Control No.: 1557–0217.

Type of Review: Regular.

Description: In 1999, the OCC issued the Interagency Guidance on Asset Securitization Activities [1] (guidance) in response to a determination that some institutions involved in asset securitization activities had significant weaknesses in their asset securitization practices. The information collection contained in the guidance applies to financial institutions engaged in asset securitization activities and provides that any institution engaged in these activities should maintain a written asset securitization policy, document the fair value of retained interests, and maintain a management information system to monitor asset securitization activities. Financial institution management uses the information collected to ensure the safe and sound operation of the institution's asset securitization activities. The OCC uses the information to evaluate the quality of an institution's risk management practices.

Affected Public: Businesses or other for-profit.

Burden Estimates:

Estimated Number of Respondents: 35 national banks and Federal savings associations.

Estimated Annual Burden: 1,827 hours.

Frequency of Response: On occasion.

On March 10, 2022, the OCC published a 60-day notice for this information collection, 87 FR 13792. No comments were received. Comments continue to be solicited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the information collection burden;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection 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.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2022–13762 Filed 6–27–22; 8:45 am]

BILLING CODE 4810–33–P

[1] OCC Bulletin 1999–46, December 13, 1999, *https://www.occ.gov/news-issuances/bulletins/1999/bulletin-1999-46a.pdf.*

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Submission for OMB Review; Survey of Minority Owned Institutions

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, 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 a continuing information collection, as required by the Paperwork Reduction Act of 1995 (PRA). An agency may not conduct or sponsor, and respondents are not required to respond to, an information collection unless it displays a currently valid Office of

Management and Budget (OMB) control number. The OCC is soliciting comment concerning a renewal of an information collection titled ''Survey of Minority Owned Institutions.'' The OCC also is giving notice that it has sent the collection to OMB for review.

DATES: Comments must be submitted on or before July 28, 2022.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email: prainfo@occ.treas.gov.*
- *Mail:* Chief Counsel's Office, Attention: Comment Processing, 1557–0236, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Fax:* (571) 465–4326.

Instructions: You must include ''OCC'' as the agency name and ''1557–0236'' in your comment. In general, the OCC will publish comments on *www.reginfo.gov* without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Written comments and recommendations for the proposed information collection should also 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.

On April 11, 2022, the OCC published a 60-day notice for this information collection, 87 FR 21262. You may review comments and other related materials that pertain to this information collection following the close of the 30-day comment period for this notice by the method set forth in the next bullet.

- *Viewing Comments Electronically:* Go to *www.reginfo.gov.* Hover over the ''Information Collection Review'' tab and click on ''Information Collection Review'' from the drop-down menu. From the ''Currently under Review'' drop-down menu, select ''Department of Treasury'' and then click ''submit.'' This information collection can be located by searching by OMB control number ''1557–0236'' or ''Survey of Minority Owned Institutions.'' Upon finding the appropriate information collection, click on the related ''ICR Reference Number.'' On the next screen, select ''View Supporting Statement and Other Documents'' and then click on the link to any comment listed at the bottom of the screen.
- For assistance in navigating *www.reginfo.gov,* please contact the Regulatory Information Service Center at (202) 482–7340.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, Clearance Officer, (202) 649–5490, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the OMB for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The OCC asks that OMB extend its approval of the collection of information in this document.

Title: Survey of Minority Owned Institutions.

OMB Control No.: 1557–0236.

Type of Review: Regular review.

Description: The OCC is committed to assessing its efforts to provide supervisory support, technical assistance, education, and other outreach to the minority-owned institutions under its supervision, in accordance with meeting the goals prescribed under section 308 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989.[1] To perform this assessment, it is necessary to obtain feedback from the individual institutions on the effectiveness of the OCC's current efforts in these areas and suggestions on how the OCC might enhance or augment its supervision and technical assistance going forward. The OCC uses the information gathered to assess the needs of minority-owned institutions and its efforts to meet those needs. The OCC also uses the information to focus and enhance its supervisory, technical assistance, education, and other outreach activities with respect to minority-owned institutions.

Affected Public: Businesses or other for-profit.

Type of Review: Regular.

Estimated Number of Respondents: 55.

Estimated Annual Burden: 110 hours.

Frequency of Response: On occasion.

On April 11, 2022, the OCC published a 60-day notice for this information collection, 87 FR 21262. No comments were received. Comments continue to be invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the information collection burden;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection 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.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2022–13759 Filed 6–27–22; 8:45 am]

BILLING CODE 4810–33–P

[1] 12 U.S.C. 1463 note.

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Proposed Collection of Information: Notice of Reclamation—Electronic Funds Transfer, Federal Recurring Payment

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the Notice of Reclamation—Electronic Funds Transfer, Federal Recurring Payment.

DATES: Written comments should be received on or before August 29, 2022 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A. Sharp, Room #4006–A, PO Box 1328, Parkersburg, WV 26106–1328, or *bruce.sharp@fiscal.treasury.gov.*

SUPPLEMENTARY INFORMATION:

Title: Notice of Reclamation—Electronic Funds Transfer, Federal Recurring Payment.

OMB Number: 1530–0003.

Form Number: FS Form 133.

Abstract: FS Form 133 is utilized to notify financial institutions of an obligation to repay payments erroneously issued to a deceased Federal benefit payment recipient. The information collected from the financial institutions is used by Treasury to close out the request from a program agency to collect an EFT payment from the financial institution to which a beneficiary was not entitled.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 223,128.

Estimated Time per Respondent: 8 minutes.

Estimated Total Annual Burden Hours: 29,750.

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: 1. 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; 2. the accuracy of the agency's estimate of the burden of the collection of information; 3. ways to enhance the quality, utility, and clarity of the information to be collected; 4. ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and 5. estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: June 21, 2022.

Bruce A. Sharp,

Bureau PRA Clearance Officer.

[FR Doc. 2022–13711 Filed 6–27–22; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–XXXX]

Agency Information Collection Activity: Guaranteed or Insured Loan Reporting Requirements

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice; withdrawal.

SUMMARY: On Wednesday, June 22, 2022 the Veterans Benefits Administration (VA), published a notice in the **Federal Register** announcing an opportunity for public comment on the proposed collection of Guaranteed or Insured Loan Reporting Requirements. This notice was published in error; therefore, this document corrects that error by withdrawing this FR notice, document number 2022–13257.

DATES: As of Thursday, June 23, 2022, the FR notice published at 87 FR 13257 on Wednesday, June 22, 2022, is withdrawn.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.*

SUPPLEMENTARY INFORMATION: FR Doc. 2022–13257, published on June 22, 2022, 87 FR 13257), is withdrawn by this notice.

By direction of the Secretary:

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2022–13761 Filed 6–27–22; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0864]

Agency Information Collection Activity: Department of Veterans Affairs (VA) Post-Separation Transition Assistance Program (TAP) Assessment

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before August 29, 2022.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *nancy.kessinger.@va.gov.* Please refer to ''OMB Control No. 2900–0864'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0864'' in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA'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 respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: Executive Order 13571—Streamlining Service Delivery and Improving Customer Service.

Title: Department of Veterans Affairs (VA) Post-Separation Transition Assistance Program (TAP) Assessment.

OMB Control Number: 2900–0864.

Type of Review: Extension of a currently approved collection.

Abstract: The PSTAP Assessment is administered by VA to assess how the TAP training for Transitioning Service members (TSMs) prepares Veterans for civilian life and its effects on long-term Veteran outcomes. This information collection request (ICR) is conducted once per year and is designed as two separate collections which include a Cross-Sectional Survey and a Longitudinal Survey. The survey population for the Cross-Sectional Survey includes all Veterans who meet the criteria at the time of fielding of having separated from the military at six months, one year, and three years prior to the date that surveys. Service members who participated in the Cross-Sectional Survey and voluntarily agreed to participate in the Longitudinal Survey make up the Longitudinal Survey population. VA will use email and mail methods to administer the survey, limiting the burden on respondents. The surveys will be administered to gauge the long-term effectiveness of the Transition Assistance Program (TAP) by: (1) examining the relationship between attendance in TAP courses and the use of VA Benefits; (2) analyzing the effect of participation in TAP courses on the long-term outcomes of Veterans in the broad life domains of employment, education, health and social relationships, financial, social connectivity and overall satisfaction and well-being, and; (3) identifying areas of improvement for TAP and the broader transition process to guide training and/or operational activities aimed at enhancing the quality of service provided to transitioning service members, Veterans, their families and caregivers.

Affected Public: Individuals.

Estimated Annual Burden: 5,954 hours.

Estimated Average Burden per Respondent: 18.5 minutes.

Frequency of Response: Annual.

Estimated Number of Respondents: 19,311.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2022–13765 Filed 6–27–22; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Rehabilitation Research and Development Service Scientific Merit Review Board; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act (5 U.S.C. app.2), that a meeting of the Rehabilitation Research and Development Service Scientific Merit Review Board (hereinafter the Board) will be held on Wednesday, August 24, 2022, via Webex. The meeting will be held between 1:00–1:30 p.m. EST. The meeting will be partially closed to the public from 1:10–1:30 p.m. EST for the discussion, examination and reference to the research applications and scientific review.

Discussions will involve reference to staff and consultant critiques of research proposals. Discussions will also deal with scientific merit of each proposal and qualifications of personnel conducting the studies, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. Additionally, premature disclosure of research information could significantly obstruct implementation of proposed agency action regarding the research proposals. As provided by Public Law 92–463 subsection 10(d), as amended by Public Law 94–409, closing the Board meeting is in accordance with 5 U.S.C. 552b(c) (6) and (9)(B).

The objective of the Board is to provide for the fair and equitable selection of the most meritorious research projects for support by VA research funds and to offer advice for research program officials on program priorities and policies. The ultimate objective of the Board is to ensure that the VA Rehabilitation Research and Development program promotes functional independence and improves the quality of life for impaired and disabled Veterans.

Board members advise the Director, Rehabilitation Research and Development Service and the Chief Research and Development Officer on the scientific and technical merit, the mission relevance, and the protection of human and animal subjects of Rehabilitation Research and Development proposals. The Board does not consider grants, contracts or other forms of extramural research.

Members of the public who wish to attend the open portion of the Webex session from 1:00–1:10 p.m. EST may join by dialing the Webex USA Toll-free Number 1–833–558–0712 and entering the meeting number (access code): 2762 946 7943. Written comments from the public must be sent prior to the meeting to Tiffany Asqueri, Designated Federal Officer, Rehabilitation Research and Development Service, Department of Veterans Affairs (14RDR), 810 Vermont Avenue NW, Washington, DC 20420, or to *Tiffany.Asqueri@va.gov*. Those who plan to attend the open portion of the meeting must contact Mrs. Asqueri at least five (5) days before the meeting. For further information, please call Mrs. Asqueri at 202–568–1174.

Dated: June 23, 2022.

LaTonya L. Small,

Federal Advisory Committee Management Officer.

[FR Doc. 2022–13782 Filed 6–27–22; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Health Services Research and Development Service Scientific Merit Review Board; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. app. 2, that a meeting of the Health Services Research and Development Service Scientific Merit Review Board will be held September 1, 2022, via WebEx. The meeting will be held between noon and 1:30 p.m. EST. The meeting will be partially closed to the public from 12:15–1:30 p.m. EST for the discussion, examination and reference to the research applications and scientific review. Discussions will involve reference to staff and consultant critiques of research proposals. Discussions will deal with scientific merit of each proposal and qualifications of personnel conducting the studies, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. Additionally, premature disclosure of research information could significantly obstruct implementation of proposed agency action regarding the research proposals. As provided by Public Law 92–463 subsection 10(d), as amended by Public Law 94–409, closing the committee meeting is in accordance with 5 U.S.C. 552b(c)(6) and (9)(B).

The objective of the Board is to provide for the fair and equitable selection of the most meritorious research projects for support by VA research funds and to offer advice for research program officials on program priorities and policies. The ultimate objective of the Board is to ensure the high quality and mission relevance of VA's legislatively mandated Health

Services Research and Development program.

Board members advise the Director, Health Services Research and Development Service and the Chief Research and Development Officer on the scientific and technical merit, the mission relevance, and the protection of human subjects of Health Services Research and Development proposals. The Board does not consider grants, contracts or other forms of extramural research.

Members of the public who wish to attend the open portion of the teleconference session from 12:00–12:15 p.m. EST may join by dialing the WebEx USA Toll-free Number 1–404–397–1596 and entering the meeting number (access code): 2761 336 2549.

Written comments from the public must be sent to Tiffin Ross-Shepard, Alternate Designated Federal Officer, Health Services Research and Development Service, Department of Veterans Affairs (14RDH), 810 Vermont Avenue NW, Washington, DC 20420, or to *Tiffin.Ross-Shepard@va.gov* prior to the meeting. Those who plan to attend the open portion of the meeting must contact Ms. Ross-Shepard at least 5 days before the meeting. For further information, please call Ms. Ross-Shepard at 202–443–5776.

Dated: June 23, 2022.

LaTonya L. Small,

Federal Advisory Committee Management Officer.

[FR Doc. 2022–13780 Filed 6–27–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–XXXX]

Agency Information Collection Activity Under OMB Review: Veterans Engagement Action Center (VEAC) Surveys

AGENCY: Veterans Experience Office, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Experience Office, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Refer to 'VEAC Survey Feedback''.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''VEO VEAC Survey Feedback'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 44 U.S.C. 3501–21.

Title: Veterans Engagement Action Center (VEAC) Surveys.

OMB Control Number: None.

Type of Review: ICR.

Abstract: Veterans Experience Action Center (VEAC) is a Veterans Affairs (VA) program established to proactively assist Veterans in a selected state with a one-stop resource for all their needs. The VEAC brings together VA benefits, health care and other resources in partnership with state VA resources.

The VEAC gathers feedback from Veterans, Active Military, Guard/Reservist, Family members, caregivers, providers, and survivors. The VEAC then provides that feedback to VA leaders to measure the success of the outreach event and measure the ease, effectiveness, emotion, and trust from the participants as they exit.

The surveys will further allow the Veterans Experience Office (VEO) to measure whether the needs of the participants were met. Additional areas where the survey results will impact:

- Identifies gaps and challenges in health care, benefits, and service delivery.
- Identifies areas for how VA can best support local efforts in a holistic fashion.
- Identifies areas where there may be barriers to access, and outreach tailored to local communities.

Per FY2021 MILCON House report 116–445, the Committee directs the VA to provide quarterly reports on the status of the implementation of the VEAC pilot program; the effectiveness of the pilot program at reaching Veterans, particularly those in need, and increasing utilization of VA services:

- Congress (Quarterly Congressional Tracking Reports (CTRs)

VEAC surveys afford VEAC participants the ability to provide feedback to VA and allow the customer to share their experiences. VEO uses the customer's feedback to enhance and increase outreach and engagement efforts and determine the direct value of our efforts.

The surveys and its delivery are an innovative approach to measure and improve customer experience based on the ''voice of the Veteran.'' Through the use of the VSignals digital platform, VEO can identify gaps and challenges in the community, provide information on VA programs, increase access and outreach, identify what is and what is not working, and determine how VA can best support local community efforts in support of Veterans, families, caregivers, and survivors. The Veteran Experience Office (VEO) has also been commissioned to measure the satisfaction of Peer-to-Peer organizations and veterans who recently interacted with the VEAC.

Survey respondents will be Veterans, Active Military, Guard/Reservist, family members, caregivers, and survivors that attend a VEAC event. Some VEAC participants may also be offered to provide feedback to surveys that capture their experience through their Peer-to-Peer connections or their attendance on a Veterans Experience Live Question and Answer event. Different surveys may be administered participants of events:

1. *VEAC Exit Survey:* Outreach event staff will verbally administer the survey to event attendees as the last step in the overall event process. The outreach staff will fill out the web-based survey on behalf of the outreach event participant.

2. *VEAC Email Survey:* A survey will be sent via email to event attendees that were not able to take the VEAC Exit Survey. The email survey will not be sent to event attendees that opted out of the VEAC Exit Survey.

3. *Peer-to-Peer Survey:* The survey is completed via an email-based survey design. After a Peer-to-Peer organization interacts with a VEAC Representative, the VEAC Representative will send an email to the Peer-to-Peer organization with a link to the Vsignals survey. The Peer-to-Peer organization can take the survey and share the survey to Veterans via email at the conclusion of each Peer-to-Peer interaction. Peer-to-Peer organizations and veterans will choose whether they want to participate in the survey.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection

of information was published at 87 FR 24225, Publication Date:04/22/2022, pages: 24225–24226.

Affected Public: Individuals.

Estimated Annual Burden: 1,200 hours.

Estimated Average Burden per Respondent: 4 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 16,000.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2022–13751 Filed 6–27–22; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 512

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 512

[CMS–1768–P]

RIN 0938–AU79

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would update and revise the End-Stage Renal Disease (ESRD) Prospective Payment System for calendar year 2023. This proposed rule also proposes to update the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury. This rule also includes requests for information regarding potential payment adjustments for certain new renal dialysis drugs and biological products as well as health equity issues under the ESRD PPS with a focus on pediatric dialysis payment. In addition, this proposed rule proposes to update requirements for the ESRD Quality Incentive Program. Finally, this proposed rule would make updates to the ESRD Treatment Choices Model.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by August 22, 2022.

ADDRESSES: In commenting, please refer to file code CMS–1768–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1768–P, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1768–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

ESRDPayment@cms.hhs.gov, for issues related to the ESRD PPS and coverage and payment for renal dialysis services furnished to individuals with AKI.

ESRDApplications@cms.hhs.gov, for issues related to applications for the Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) or the Transitional Drug Add-on Payment Adjustment (TDAPA).

Delia Houseal, (410) 786–2724, for issues related to the ESRD QIP.

ETC-CMMI@cms.hhs.gov, for issues related to the ESRD Treatment Choices (ETC) Model.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Current Procedural Terminology (CPT) Copyright Notice: Throughout this proposed rule, we use CPT® codes and descriptions to refer to a variety of services. We note that CPT® codes and descriptions are copyright 2020 American Medical Association (AMA). All Rights Reserved. CPT® is a registered trademark of the AMA. Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a Table of Contents.

I. Executive Summary

A. Purpose

This rule proposes changes related to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), payment for renal dialysis services furnished to individuals with acute

kidney injury (AKI), the ESRD Quality Incentive Program (QIP), and the ESRD Treatment Choices (ETC) Model.

1. End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This proposed rule would update the ESRD PPS for CY 2023.

2. Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

On June 29, 2015, the President signed the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27). Section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a new subsection (r) that provides for payment for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate beginning January 1, 2017. This proposed rule would update the AKI payment rate for CY 2023.

3. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

The End-Stage Renal Disease Quality Incentive Program (ESRD QIP) is authorized by section 1881(h) of the Act. The Program fosters improved patient outcomes by establishing incentives for facilities to meet or exceed performance standards established by the Centers for Medicare & Medicaid Services (CMS). This proposed rule proposes several updates for Payment Year (PY) 2023, including the suppression of individual ESRD QIP measures for PY 2023 under the measure suppression policy previously finalized for the duration of the COVID–19 public health emergency (PHE), as well as updates for PY 2024 and PY 2025. At this time, no new requirements are being proposed beginning with the PY 2026 ESRD QIP.

4. End-Stage Renal Disease Treatment Choices (ETC) Model

The ETC Model is a mandatory Medicare payment model tested under section 1115A of the Act. The ETC Model is operated by the Center for Medicare and Medicaid Innovation (Innovation Center), and tests the use of payment adjustments to encourage greater utilization of home dialysis and kidney transplants, to preserve or enhance the quality of care furnished to Medicare beneficiaries while reducing Medicare expenditures. The ETC Model was finalized as part of a final rule published in the **Federal Register** on September 29, 2020, titled, ''Medicare Program: Specialty Care Models to Improve Quality of Care and Reduce Expenditures'' (85 FR 61114), referred to herein as the ''Specialty Care Models final rule.'' This proposed rule would make certain changes to the ETC Model, including adding a parameter to the Performance Payment Adjustment (PPA) achievement scoring methodology and adding an additional protection related to flexibilities for furnishing and billing kidney disease patient education services by ETC Participants. This proposed rule also discusses our intent to disseminate participant-level model performance information to the public.

B. Summary of the Major Provisions

1. ESRD PPS

- *Rebasing and revision of the End-Stage Renal Disease Bundled (ESRDB) market basket for CY 2023:* We are proposing to rebase and revise the ESRDB market basket to a 2020 base year, reflecting the most recent and complete set of Medicare Cost Report data as well as other publicly available data. In addition, we are proposing to update the labor-related share of the ESRD PPS base rate to reflect the proposed 2020 labor-related cost share weights designated in the ESRDB market basket.
- *Update to the ESRD PPS base rate for CY 2023:* The proposed CY 2023 ESRD PPS base rate is $264.09. This proposed amount reflects the application of the wage index budget-neutrality adjustment factor (0.999997) and a proposed productivity-adjusted market basket increase of 2.4 percent as required by section 1881(b)(14)(F)(i)(I) of the Act, equaling $264.09 (($257.90 × 0.999997) × 1.024 = $264.09).
- *Annual update to the wage index:* We adjust wage indices on an annual basis using the most current hospital wage data and the latest core-based statistical area (CBSA) delineations to account for differing wage levels in areas in which ESRD facilities are located. For CY 2023, we are proposing to update the wage index values based on the latest available data.
- *Permanent cap on wage index decreases:* For CY 2023 and subsequent years, we are proposing to apply a permanent 5-percent cap on any ESRD facility's wage index decrease from its wage index in the prior year, regardless of the circumstances causing the decline.
- *Wage index floor:* We are proposing to raise the wage index floor, for areas with wage index values below the floor, from 0.5000 to 0.6000.
- *Outlier policy refinement:* The ESRD PPS has an outlier policy that targets 1.0 percent of total Medicare ESRD PPS expenditures in outlier payments for ESRD beneficiaries who require a high level of renal dialysis services. We are proposing to modify the methodology for calculating the fixed-dollar loss (FDL) amounts for adult patients.
- *Annual update to the outlier policy:* We are proposing to update the outlier policy based on the most current data and our proposed refinement to the outlier policy. Accordingly, we propose to update the Medicare allowable payment (MAP) amounts for adult and pediatric patients for CY 2023 using the latest available CY 2021 claims data. We propose to update the ESRD outlier services FDL amount for pediatric patients using the latest available CY 2021 claims data, and we propose to use the latest available claims data from CY 2019, CY 2020, and CY 2021 to calculate the FDL amount for adults, in accordance with the proposed methodology discussed in section II.B.1.c.(4) of this proposed rule. For pediatric beneficiaries, the proposed FDL amount would decrease from $26.02 to $21.51, and the proposed MAP amount would decrease from $27.15 to $25.62, as compared to CY 2022 values. For adult beneficiaries, the proposed FDL amount would decrease from $75.39 to $40.75, and the proposed MAP amount would decrease from $42.75 to $36.85. The 1.0 percent target for outlier payments was not achieved in CY 2021. Outlier payments represented approximately 0.4 percent

of total payments rather than 1.0 percent.

- *Definition of oral-only drugs:* We are proposing that, beginning January 1, 2025, we would include the word functional in the definition of oral-only drug at § 413.234(a). Specifically, under the proposed definition, an oral-only drug would be a drug or biological product with no injectable *functional* equivalent or other form of administration other than an oral form.
- *Update to the offset amount for the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) for CY 2023:* The proposed CY 2023 average per treatment offset amount for the TPNIES for capital-related assets that are home dialysis machines is $9.73. This proposed offset amount reflects the application of the productivity-adjusted market basket increase of 2.4 percent ($9.50 × 1.024 = $9.73).
- *TPNIES applications received for CY 2023:* This proposed rule presents a summary of the three CY 2023 TPNIES applications that we received by the February 1, 2022 deadline and our preliminary analysis of the applicants' claims related to substantial clinical improvement and other eligibility criteria for the TPNIES.

2. Payment for Renal Dialysis Services Furnished to Individuals With AKI

We are proposing to update the AKI payment rate for CY 2023. The proposed CY 2023 payment rate is $264.09, which is the same as the base rate proposed under the ESRD PPS for CY 2023.

3. ESRD QIP

We are proposing to suppress the Standardized Hospitalization Ratio (SHR) clinical measure, the Standardized Readmission Ratio (SRR) clinical measure, the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) clinical measure, the Long-Term Catheter Rate clinical measure, the Percentage of Prevalent Patients Waitlisted (PPPW) clinical measure, and the Kt/V Dialysis Adequacy Comprehensive clinical measure for PY 2023 under our previously finalized measure suppression policy because we have determined that circumstances caused by the public health emergency (PHE) due to COVID–19 have significantly affected the measures and resulting performance scores. We are also proposing to use CY 2019 data to calculate performance standards for the PY 2023 ESRD QIP. We are also updating the technical specifications of the SHR clinical measure and SRR clinical measure so that the measure results are expressed as rates instead of ratios beginning with the PY 2024 ESRD QIP. Beginning with the PY 2025 ESRD QIP, we are proposing to add the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure to the ESRD QIP measure set. We are also proposing to convert the Standardized Transfusion Ratio (STrR) reporting measure to a clinical measure beginning with PY 2025, and are further proposing to express the measure as a rate to align with the technical updates to express the SHR and SRR clinical measure results as rates. In addition, we are proposing to convert the Hypercalcemia clinical measure to a reporting measure, beginning with PY 2025. Furthermore, we are proposing to create a new Reporting Measure domain and to re-weight current measure domains beginning with PY 2025.

This proposed rule also includes requests for information on several important topics, including potential quality measures for home dialysis, the expansion of our quality reporting programs to allow us to provide more actionable and comprehensive information on health care disparities across multiple variables and new care settings, and on the possible future inclusion of two potential social drivers of health screening measures.

4. ETC Model

We are proposing to update the PPA achievement scoring methodology beginning in the fifth Measurement Year (MY5) of the ETC Model, which begins January 1, 2023. We are also proposing to clarify the requirements for qualified staff to furnish and bill kidney disease patient education services under the ETC Model's Medicare program waivers. In addition, we discuss our intent to disseminate participant-level model performance information to the public.

C. Summary of Costs and Benefits

In section VII.D.5 of this proposed rule, we set forth a detailed analysis of the impacts that the proposed changes would have on affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Proposed ESRD PPS

The impact table in section VII.D.5.a of this proposed rule displays the estimated change in payments to ESRD facilities in CY 2023 compared to estimated payments in CY 2022. The overall impact of the CY 2023 changes is projected to be a 3.1 percent increase in payments. Hospital-based ESRD facilities have an estimated 3.7 percent increase in payments compared with freestanding facilities with an estimated 3.1 percent increase. We estimate that the aggregate ESRD PPS expenditures would increase by approximately $320 million in CY 2023 compared to CY 2022. This reflects a $250 million increase from the proposed payment rate update, a $70 million increase due to the proposed updates to the outlier threshold amounts, and approximately $2.5 million in estimated TPNIES amounts. Because of the projected 3.1 percent overall payment increase, we estimate there would be an increase in beneficiary coinsurance payments of 3.1 percent in CY 2023, which translates to approximately $60 million.

2. Impacts of the Proposed Payment for Renal Dialysis Services Furnished to Individuals With AKI

The impact table in section VII.D.5.b of this proposed rule displays the estimated change in payments to ESRD facilities in CY 2023 compared to estimated payments in CY 2022. The overall impact of the CY 2023 changes is projected to be a 2.4 percent increase in payments for individuals with AKI. Hospital-based ESRD facilities have an estimated 2.1 percent increase in payments compared with freestanding ESRD facilities with an estimated 2.4 percent increase. The overall impact reflects the effects of the proposed update to the labor-related share, proposed CY 2023 wage index, proposed permanent cap on wage index decreases, and the proposed payment rate update. We estimate that the aggregate payments made to ESRD facilities for renal dialysis services furnished to patients with AKI, at the proposed CY 2023 ESRD PPS base rate, would increase by $2 million in CY 2023 compared to CY 2022.

3. Impacts of the Proposed ESRD QIP

Our proposals to suppress measures for the PY 2023 ESRD QIP necessitate a modification to our previously estimated overall economic impact of the PY 2023 ESRD QIP (85 FR 71400). In the CY 2021 ESRD PPS final rule, we estimated that the overall economic impact of the PY 2023 ESRD QIP would be approximately $224 million as a result of the policies we had finalized at that time. The $224 million figure for PY 2023 included costs associated with the collection of information requirements, which we estimated would be approximately $208 million, and $16 million in estimated payment reductions across all facilities. However, as a result of the proposals impacting the PY 2023 ESRD QIP that we are making in this proposed rule, we are modifying our previous estimate. We now estimate that the overall economic

impact of the PY 2023 ESRD QIP would be approximately $218 million. The $218 million figure for PY 2023 includes costs associated with the collection of information requirements and recalculated estimated payment reductions based on the six measures we are proposing to suppress for PY 2023. Although we are updating the way we express the SHR clinical measure and the SRR clinical measure results beginning with PY 2024, these technical updates would not impact our previously estimated economic impact for the PY 2024 ESRD QIP. We estimate that the overall economic impact of the PY 2025 ESRD QIP would be approximately $252 million as a result of the policies we have previously finalized and the proposals in this proposed rule. The $252 million figure for PY 2025 includes costs associated with the collection of information requirements, which we estimate would be approximately $215 million, and $37 million in estimated payment reductions across all facilities. We also estimate that the overall economic impact of the PY 2026 ESRD QIP would be approximately $252 million as a result of the policies we have previously finalized. The $252 million figure for PY 2026 includes costs associated with the collection of information requirements, which we estimate would be approximately $215 million, and $37 million in estimated payment reductions across all facilities.

4. Impacts of the Proposed Changes to the ETC Model

The impact estimate in section VII.D.5.d of this proposed rule describes the estimated change in anticipated Medicare program savings arising from the ETC Model over the duration of the ETC Model as a result of the proposed changes. We estimate that the ETC Model would result in $28 million in net savings over the 6.5 year duration of the ETC Model. We also estimate that the changes proposed in this proposed rule would produce no change in net savings for the ETC Model.

II. CY 2023 ESRD PPS

A. Background

1. Statutory Background

On January 1, 2011, CMS implemented the ESRD PPS, a case-mix adjusted bundled PPS for renal dialysis services furnished by ESRD facilities, as required by section 1881(b)(14) of the Act, as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act), established that beginning with CY 2012, and each subsequent year, the Secretary shall annually increase payment amounts by an ESRD market basket increase factor reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 632 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240) included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2012, to reduce the single payment for renal dialysis services furnished on or after January 1, 2014, to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals (excluding oral-only ESRD-related drugs). Consistent with this requirement, in the CY 2014 ESRD PPS final rule, we finalized $29.93 as the total drug utilization reduction and finalized a policy to implement the amount over a 3- to 4-year transition period (78 FR 72161 through 72170).

Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS prior to January 1, 2016. Section 632(c) of ATRA required the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted. Section 217 of PAMA included several provisions that apply to the ESRD PPS. Specifically, sections 217(b)(1) and (2) of PAMA amended sections 1881(b)(14)(F) and (I) of the Act and replaced the drug utilization adjustment that was finalized in the CY 2014 ESRD PPS final rule (78 FR 72161 through 72170) with specific provisions that dictated the market basket update for CY 2015 (0.0 percent) and how the market basket should be reduced in CY 2016 through CY 2018.

Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to provide that the Secretary may not pay for oral-only ESRD-related drugs under the ESRD PPS prior to January 1, 2024. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by requiring that in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the most recent year available. Section 217(c) of PAMA provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for—(1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment.

Finally, on December 19, 2014, the President signed the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295). Section 204 of ABLE amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis services cannot be made under the ESRD PPS bundled payment prior to January 1, 2025.

2. System for Payment of Renal Dialysis Services

Under the ESRD PPS, a single per-treatment payment is made to an ESRD facility for all the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to individuals for the treatment of ESRD in the ESRD facility or in a patient's home. We have codified our definition of renal dialysis services at § 413.171, which is in 42 CFR part 413, subpart H, along with other ESRD PPS payment policies. The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients and accounts for patient case-mix variability. The adult case-mix adjusters include five categories of age, body surface area, low body mass index, onset of dialysis, and four comorbidity categories (that is, pericarditis, gastrointestinal tract bleeding, hereditary hemolytic or sickle cell anemia, myelodysplastic syndrome). A different set of case-mix adjusters are applied for the pediatric population. Pediatric patient-level adjusters include two age categories (under age 22, or age 22 to 26) and two dialysis modalities (that is, peritoneal or hemodialysis) (§ 413.235(a) and (b)).

The ESRD PPS provides for three facility-level adjustments. The first payment adjustment accounts for ESRD facilities furnishing a low volume of dialysis treatments (§ 413.232). The second payment adjustment reflects differences in area wage levels developed from core-based statistical areas (CBSAs) (§ 413.231). The third payment adjustment accounts for ESRD facilities furnishing renal dialysis services in a rural area (§ 413.233).

There are four additional payment adjustments under the ESRD PPS. The ESRD PPS provides adjustments, when applicable, for: (1) a training add-on for home and self-dialysis modalities (§ 413.235(c)); (2) an additional payment

for high cost outliers due to unusual variations in the type or amount of medically necessary care (§ 413.237); (3) a TDAPA for certain new renal dialysis drugs and biological products (§ 413.234(c)); and (4) a TPNIES for certain qualifying, new and innovative renal dialysis equipment and supplies (§ 413.236(d)).

3. Updates to the ESRD PPS

Policy changes to the ESRD PPS are proposed and finalized annually in the **Federal Register**. The CY 2011 ESRD PPS final rule was published on August 12, 2010 in the **Federal Register** (75 FR 49030 through 49214). That rule implemented the ESRD PPS beginning on January 1, 2011 in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA, over a 4-year transition period. Since the implementation of the ESRD PPS, we have published annual rules to make routine updates, policy changes, and clarifications.

We published a final rule, which appeared in the November 8, 2021 issue of the **Federal Register**, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model,'' referred to herein as the ''CY 2022 ESRD PPS final rule.'' In that rule, we updated the ESRD PPS base rate, wage index, and outlier policy for CY 2022. We also updated the average per treatment offset amount for the TPNIES for CY 2022. In addition, we announced our approval of one application for the TPNIES for CY 2022 payment. For further detailed information regarding these updates, see 86 FR 61874.

B. Provisions of the Proposed Rule

1. Proposed CY 2023 ESRD PPS Update

a. Proposed CY 2023 ESRD Bundled (ESRDB) Market Basket Rebasing and Revision; Market Basket Increase Factor; Productivity Adjustment; and Labor-Related Share

(1) Proposed Rebasing and Revising of the ESRDB Market Basket

(a) Background

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket increase factor and reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment may result in the increase factor being less than 0.0 for a year and may result in payment rates for a year being less than the payment rates for the preceding year. Section 1881(b)(14)(F)(i) of the Act also provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services.

As required under section 1881(b)(14)(F)(i) of the Act, CMS developed an all-inclusive ESRD Bundled (ESRDB) input price index using CY 2008 as the base year (75 FR 49151 through 49162). We subsequently revised and rebased the ESRDB input price index to a base year of CY 2012 in the CY 2015 ESRD PPS final rule (79 FR 66129 through 66136). In the CY 2019 ESRD PPS final rule (83 FR 56951 through 56964), we finalized a rebased ESRDB input price index to reflect a CY 2016 base year. Effective for CY 2023, we are proposing to rebase and revise the ESRDB market basket to a base year of CY 2020.

Although ''market basket'' technically describes the mix of goods and services used for ESRD treatment, this term is also commonly used to denote the input price index (that is, cost categories, their respective weights, and price proxies combined) derived from a market basket. Accordingly, the term ''ESRDB market basket,'' as used in this document, refers to the ESRDB input price index.

The ESRDB market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres-type price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time are not measured.

The index is constructed in three steps. First, a base period is selected where total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called ''cost weights'' or ''expenditure weights.'' Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a ''price proxy.'' In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price index levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As noted previously, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services purchased to provide renal dialysis services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, an ESRD facility hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the ESRD facility, but would not be factored into the price change measured by a fixed-weight ESRD market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect changes between base periods in the mix of goods and services that ESRD facilities purchase to furnish ESRD treatment.

We last rebased the ESRDB market basket cost weights effective for CY 2019 (83 FR 56951 through 56964), with 2016 data used as the base period for the construction of the market basket cost weights. We are proposing to use 2020 as the base year for the proposed rebased ESRDB market basket cost weights. The cost weights for this proposed ESRDB market basket are based on the cost report data for independent ESRD facilities. We refer to the proposed market basket as a CY market basket because the base period for all price proxies and weights are set to CY 2020 (that is, the average index level for CY 2020 is equal to 100). The major source data for the proposed ESRDB market basket is the 2020 Medicare cost reports (MCRs) (Form CMS–265–11, OMB NO. 0938–0236), supplemented with 2012 data from the United States (U.S.) Census Bureau's Services Annual Survey (SAS) inflated to 2020 levels. The 2012 SAS data is the most recent year of detailed expense data published by the Census Bureau for North American International Classification System (NAICS) Code 621492: Kidney Dialysis Centers. We also are proposing to use May 2020

Occupational Employment Statistics data from the U.S. Department of Labor's Bureau of Labor Statistics (BLS) to estimate the weights for the Wages and Salaries and Employee Benefits occupational blends. We provide more detail on our proposed methodology in section II.B.1.a.(1)(b) of this proposed rule.

The terms ''rebasing'' and ''revising,'' while often used interchangeably, actually denote different activities. The term ''rebasing'' means moving the base year for the structure of costs of an input price index (that is, in this exercise, we are proposing to move the base year cost structure from 2016 to 2020) without making any other major changes to the methodology. The term ''revising'' means changing data sources, cost categories, and/or price proxies used in the input price index. For CY 2023, we are proposing to rebase the ESRDB market basket to reflect the 2020 cost structure of ESRD facilities and to revise the index, that is, make changes to cost categories or price proxies used in the index.

We are proposing CY 2020 as the new base year because 2020 is the most recent year for which relatively complete MCR data are available. We analyzed the cost weights for the years 2017 through 2020 and found that the expenses reported in the ESRD facility MCRs for 2020 were consistent with those in the prior years. Additionally, given the nature of renal dialysis services, any impacts on utilization due to the COVID–19 PHE were minimal as dialysis is not an optional treatment and must continue even during the PHE. In developing the proposed market basket, we reviewed ESRD expenditure data from ESRD MCRs (CMS Form 265–11, OMB NO. 0938–0236) for 2020 for each freestanding ESRD facility that reported expenses and payments. The 2020 MCRs are for those ESRD facilities whose cost reporting period began on or after October 1, 2019, and before October 1, 2020. Of the 2020 MCRs, approximately 91 percent of freestanding ESRD facilities had a begin date on January 1, 2020, approximately 5 percent had a begin date prior to January 1, 2020, and approximately 4 percent had a begin date after January 1, 2020. Using this methodology allowed our sample to include ESRD facilities with varying cost report years including, but not limited to, the federal fiscal year (FY) or CY.

We are proposing to maintain our policy of using data from freestanding ESRD facilities (which account for over 90 percent of total ESRD facilities in CY 2020) because freestanding ESRD facility data reflect the actual cost structure faced by the ESRD facility itself. In contrast, expense data for hospital-based ESRD facilities reflect the allocation of overhead from the entire institution.

We developed cost category weights for the proposed 2020-based ESRDB market basket in two stages. First, we derived base year cost weights for ten major categories (Wages and Salaries, Employee Benefits, Pharmaceuticals, Supplies, Laboratory Services, Housekeeping, Operations & Maintenance, Administrative & General, Capital-Related Building and Fixtures, and Capital-Related Moveable Equipment) from the ESRD MCRs. Second, we are proposing to divide the Administrative & General cost category into further detail using 2012 SAS data for the industry Kidney Dialysis Centers NAICS 621492 inflated to 2020 levels. We apply the estimated 2020 distributions from the SAS data to the 2020 Administrative & General cost weight to yield the more detailed 2020 cost weights in the proposed market basket. This is the same methodology we used in the CY 2019 ESRD PPS rulemaking to break the Administrative & General costs into more detail for the 2016-based ESRDB market basket (83 FR 56951 through 56964).

We are proposing to include a total of 21 detailed cost categories for the proposed 2020-based ESRDB market basket, whereas the 2016-based ESRDB market basket had 20 detailed cost categories. A detailed discussion of the proposals is provided in section II.B.1.a.(1)(b) of this proposed rule.

(b) Cost Category Weights

Using Worksheets A and B from the 2020 MCRs, we first computed cost shares for ten major expenditure categories: Wages and Salaries, Employee Benefits, Pharmaceuticals, Supplies, Laboratory Services, Housekeeping, Operations & Maintenance, Administrative and General, Capital-Related Building and Fixtures, and Capital-Related Moveable Equipment. Edits were applied to include only cost reports that had total costs greater than zero. Total costs as reported on the MCR include those costs reimbursable under the ESRD PPS. For example, we excluded expenses related to vaccine costs from total expenditures since these are not paid for under the ESRD PPS.

In order to reduce potential distortions from outliers in the calculation of the individual cost weights for the major expenditure categories for each cost category, values less than the 5th percentile or greater than the 95th percentile were excluded from the major cost weight computations. The proposed data set, after removing cost reports with total costs equal to or less than zero and excluding outliers, included information from approximately 6,625 independent ESRD facilities' cost reports from an available pool of 7,413 cost reports.

Table 1 presents the proposed 2020-based ESRDB and 2016-based ESRDB market basket major cost weights as derived directly from the MCR data.

TABLE 1: Proposed 2020-based ESRDB Market Basket Major Cost Weights Derived from the Medicare Cost Report Data

Cost Category	Proposed 2020-based ESRDB Market Basket (%)	2016-based ESRDB Market Basket (%)
Wages and Salaries	34.5	32.6
Employee Benefits	7.7	7.0
Pharmaceuticals	10.1	12.4
Supplies	11.0	10.4
Laboratory Services	1.3	2.2
Housekeeping*	0.5	3.9
Operations & Maintenance	3.7	n/a
Administrative & General	17.5	18.5
Capital-related Building and Fixtures	9.4	9.2
Capital-related Moveable Equipment	4.4	3.8

Note: Totals may not sum to 100.0 percent due to rounding.
* For the 2016-based ESRDB market basket, this category was referred to as the Housekeeping and Operations cost category. For the proposed 2020-based ESRDB market basket, the Housekeeping and Operations cost category is split into two detailed cost categories: Housekeeping and Operations & Maintenance.

We are proposing to disaggregate the Administrative & General major cost category developed from the MCR into more detail to more accurately reflect ESRD facility costs. Those categories include: Benefits, Professional Fees, Telephone, Utilities, and All Other Goods and Services. We describe below how the initially computed categories and weights from the cost reports were modified to yield the proposed 2020 ESRDB market basket expenditure categories and weights presented in this proposed rule.

Wages and Salaries

The proposed Wages and Salaries cost weight is comprised of direct patient care wages and salaries and non-direct patient care wages and salaries. Direct patient care wages and salaries for 2020 was derived from Worksheet B, column 5, lines 8 through 17 of the MCR. Non-direct patient care wages and salaries includes all other wages and salaries costs for non-health workers and physicians, which we are proposing to derive using the following steps:

Step 1: To capture the salary costs associated with non-direct patient care cost centers, we calculated salary percentages for non-direct patient care from Worksheet A of the MCR. The estimated ratios were calculated as the ratio of salary costs (Worksheet A, columns 1 and 2) to total costs (Worksheet A, column 4). The salary percentages were calculated for seven distinct cost centers: 'Operations and Maintenance of Plant' combined with 'Capital Related Costs-Renal Dialysis Equipment' (line 3 and 6), Housekeeping (line 4), Employee Health and Wellness (EH&W) Benefits for Direct Patient Care (line 8), Supplies (line 9), Laboratory (line 10), Administrative & General (line 11), and Pharmaceuticals (line 12).

Step 2: We then multiplied the salary percentages computed in step 1 by the total costs for each corresponding reimbursable cost center totals as reported on Worksheet B. The Worksheet B totals were based on the sum of reimbursable costs reported on lines 8 through 17. For example, the salary percentage for Supplies (as measured by line 9 on Worksheet A) was applied to the total expenses for the Supplies cost center (the sum of costs reported on Worksheet B, column 7, lines 8 through 17). This provided us with an estimate of Non-Direct Patient Care Wages and Salaries.

Step 3: The estimated Wages and Salaries for each of the cost centers on Worksheet B derived in step 2 were subsequently summed and added to the direct patient care wages and salaries costs.

Step 4: The estimated non-direct patient care wages and salaries (see step 2) were then subtracted from their respective cost categories to avoid double-counting their values in the total costs.

Using this methodology, we derive a proposed Wages and Salaries cost weight of 34.5 percent, reflecting an estimated direct patient care wages and salaries cost weight of 25.7 percent and non-direct patient care wages and salaries cost weight of 8.9 percent, as seen in Table 2.

The final adjustment made to this category is to include Contract Labor costs. These costs appear on the MCR; however, they are embedded in the Other Costs from the trial balance reported on Worksheet A, Column 3 and cannot be disentangled using the MCRs. To avoid double counting of these expenses we are proposing to move the estimated cost weight for the contract labor costs from the Administrative and General category (where we believe the majority of the contract labor costs would be reported) to the Wages and Salaries category. We are proposing to use data from the SAS (2012 data inflated to 2020), which reported 2.4 percent of total expenses were spent on contract labor costs. We allocated 80 percent of that contract labor cost weight to the Wages and Salaries category. At the same time, we subtracted that same amount from the Administrative and General category, where the majority of contract labor expenses would likely be reported on the MCR. The 80 percent figure that was used was determined by taking salaries as a percentage of total compensation (excluding contract labor) from the 2020 MCR data. This is the same method that was used to allocate contract labor costs to the Wages and Salaries cost category

for the 2016-based ESRDB market basket.

The resulting proposed cost weight for Wages and Salaries increases to 36.5 percent when contract labor wages are added. The calculation of the proposed Wages and Salaries cost weight for the 2020-based ESRDB market basket is shown in Table 2 along with the similar calculation for the 2016-based ESRDB market basket.

TABLE 2: Proposed 2020 and 2016 ESRD Wages and Salaries Cost Weight Determination

Components	Proposed 2020 Cost Weight	2016 Cost Weight	Source
Wages and Salaries Direct Patient Care	25.2%	25.1%	MCR
Wages and Salaries Non-direct Patient Care	8.9%	7.5%	MCR
Contract Labor (Wages)	1.9%	1.9%	80% of SAS Contract Labor weight
Total Wages and Salaries	**36.5%**	**34.5%**	

Employee Benefits

The proposed Employee Benefits cost weight was derived from the MCR data for direct patient care and supplemented with data from the SAS (2012 data inflated to 2020) to account for non-direct patient care Employee Benefits. The MCR data only reflects Employee Benefit costs associated with health and wellness; that is, it does not reflect retirement benefits.

In order to reflect the benefits related to non-direct patient care for employee health and wellness, we estimated the impact on the benefit weight using SAS. Unlike the MCR, the SAS collects detailed expenses for employee benefits including expenses related to the retirement and pension benefits. Incorporating the SAS data produced an Employee Benefits (both direct patient care and non-direct patient care) weight that was 1.3 percentage points higher (9.0 vs. 7.7) than the Employee Benefits weight for direct patient care calculated directly from the MCR. To avoid double-counting and to ensure all of the market basket weights still totaled 100 percent, we removed this additional 1.3 percentage points for Non-Direct Patient Care Employee Benefits from the Administrative and General cost category.

The final adjustment made to this category is to include contract labor benefit costs. Once again, these costs appear on the MCR; however, they are embedded in the Other Costs from the trial balance reported on Worksheet A, Column 3 and cannot be disentangled using the MCR data. Identical to our methodology previously for allocating Contract Labor Costs to Wages and Benefits, we applied 20 percent of total Contract Labor Costs, as estimated using the SAS, to the Benefits cost weight calculated from the cost reports. The 20 percent figure was determined by taking benefits as a percentage of total compensation (excluding contract labor) from the 2020 MCR data. The resulting cost weight for Employee Benefits increases to 9.5 percent when contract labor benefits are added. This is the same method that was used to allocate contract labor costs to the Benefits cost category for the 2016-based ESRDB market basket.

Table 3 compares the 2016-based Benefits cost share derivation as detailed in the CY 2019 ESRD PPS final rule (83 FR 56954) to the proposed 2020-based Benefits cost share derivation.

TABLE 3: Proposed 2020 and 2016 ESRD Employee Benefits Cost Weight Determination

Components	Proposed 2020 Cost Weight	2016 Cost Weight	Source
Employee Benefits Direct Patient Care	7.7%	7.0%	MCR
Employee Benefits Non-direct Patient Care	1.3%	1.6%	SAS
Contract Labor (Benefits)	0.5%	0.5%	20% of SAS Contract Labor weight
Total Employee Benefits	**9.5%**	**9.1%**	

Pharmaceuticals

The proposed 2020-based ESRDB market basket includes expenditures for all drugs, including formerly separately billable drugs and all other ESRD-related drugs that were covered under Medicare Part D before the ESRD PPS was implemented. We calculated a Pharmaceuticals cost weight from the following cost centers on Worksheet B, the sum of lines 8 through 17, for the following columns: column 11, ''Drugs Included in Composite Rate,'' column 12, ''Erythropoiesis stimulating agents (ESAs)''; and column 13, ''ESRD-Related and AKI -Related Drugs.'' We did not include the drug expenses for Non-ESRD Related Drugs, Supplies, and Labs as reported on line 5, column 10 or the AKI Non-Renal Related Drugs, Supplies, & Lab as reported on line 5.01 column 10 as these expenses are not included in the ESRD PPS bundled payment amount. Section 1842(o)(1)(A)(iv) of the Act requires that influenza, pneumococcal, COVID–19, and hepatitis B vaccines described in paragraph (A) or (B) of section 1861(s)(10) of the Act be paid based on 95 percent of average wholesale price (AWP) of the drug. Since these vaccines are not paid for under the ESRD PPS, we did not include expenses reported on worksheet B, column 9 line 7 in the proposed 2020-based ESRDB market basket.

Finally, to avoid double-counting, the weight for the Pharmaceuticals category was reduced to exclude the estimated share of Non-Direct Patient Care Wages and Salaries associated with the applicable pharmaceutical cost centers referenced previously. This resulted in a proposed ESRDB market basket weight for Pharmaceuticals of 10.1 percent. ESA expenditures accounted for 6.0 percentage points of the proposed Pharmaceuticals cost weight, and All Other Drugs accounted for the remaining 4.1 percentage points.

The Pharmaceuticals cost weight decreased 2.3 percentage points from the 2016-based ESRDB market basket to the proposed 2020-based ESRDB market basket (12.4 percent to 10.1 percent). Most ESRD facilities experienced a decrease in their Pharmaceuticals cost weight since 2016.

Supplies

We calculated the proposed Supplies cost weight using the costs reported in the Supplies cost center (Worksheet B, line 5 and the sum of lines 8 through 17, column 7) of the MCR. To avoid double-counting, the Supplies costs were reduced to exclude the estimated share of Non-Direct patient care Wages and Salaries associated with this cost center. The resulting proposed 2020-based ESRDB market basket weight for Supplies is 11.0 percent, approximately 0.6 percentage point higher than the weight for the 2016-based ESRDB market basket.

Laboratory Services

We calculated the proposed Laboratory Services cost weight using the costs reported in the Laboratory cost center (Worksheet B, line 5 and the sum of line 8 through 17, column 8) of the MCR. To avoid double-counting, the Laboratory Services costs were reduced to exclude the estimated share of Non-Direct Patient Care Wages and Salaries associated with this cost center. The proposed 2020-based ESRDB market basket weight for Laboratory Services is estimated at 1.3 percent, which is a 0.9 percentage point decrease from the 2016-based ESRDB market basket.

Housekeeping

We calculated the proposed Housekeeping cost weight using the costs reported on Worksheet A, line 4, column 8, of the MCR. To avoid double-counting, the weight for the Housekeeping category was reduced to exclude the estimated share of Non-Direct Patient Care Wages and Salaries associated with this cost center. These costs were divided by total costs to derive a proposed 2020-based ESRDB market basket weight for Housekeeping of 0.5 percent. For the 2016-based ESRDB market basket the cost category weight for both Housekeeping and Operations costs were combined into a single cost weight. The Housekeeping cost weight in the 2016-based ESRDB market basket would have been 0.5 percent if it had been broken out separately.

Operations & Maintenance

We are proposing a new Operations & Maintenance cost category that includes the direct expenses incurred in the operation and maintenance of the plant and equipment such as heat, light, water (excluding water treatment for dialysis purposes), air conditioning, and air treatment; the maintenance and repair of building, parking facilities, and equipment; painting; elevator maintenance; performance of minor renovation of buildings and equipment; and protecting employees, visitors, and facility property. As previously discussed, these costs had formerly been combined with the Housekeeping expenses in a single cost category for Housekeeping and Operations. The proposed 2020-based ESRDB market basket Operations & Maintenance cost category reflects the expenses for Operations & Maintenance, which also includes the costs for Water and Sewerage that was a stand alone cost category in the 2016-based ESRDB market basket. We calculated the Operations & Maintenance cost weight using the costs reported on Worksheet A, line 3, column 8, of the MCR. To avoid double-counting, the weight for the Operations & Maintenance category was reduced to exclude the estimated share of Non-Direct Patient Care Wages and Salaries associated with this cost center. The resulting proposed 2020-based ESRDB market basket weight for Operations & Maintenance is 3.7 percent.

Capital

We developed a proposed market basket weight for the Capital category using data from Worksheet B of the MCRs. Capital-related costs include depreciation and lease expenses for buildings, fixtures and movable equipment, property taxes, insurance costs, the costs of capital improvements, and maintenance expense for buildings, fixtures, and machinery. The MCR captures Capital-related Costs including: (1) Capital-Related- Building and Fixtures (2) Capital-Related Costs—Moveable Equipment and (3) Housekeeping, and Operations & Maintenance costs in Worksheet B, column 2. Since we developed separate expenditure categories for Housekeeping, and Operations & Maintenance, as detailed previously, we excluded these costs from the Capital cost weights. To calculate the Capital-related Buildings and Fixtures cost weight we sum expenses reported in Worksheet B lines 8 through 17, column 2 less Housekeeping, Operations & Maintenance (as derived from expenses reported on Worksheet A, as described previously), and less Capital-related Moveable equipment costs (calculated as Worksheet A, column 8, line 2 divided by the sum of Worksheet A, column 8, lines 1 and 2). The Capital-related moveable equipment cost weight is equal to Capital-related Renal Dialysis Equipment costs (Worksheet B, the sum of lines 8 through 17, column 4 plus Capital-Related Moveable Equipment (as described in the prior sentence)). We reasoned this delineation was particularly important given the critical role played by dialysis machines. Likewise, because price changes associated with Buildings and Fixtures could move differently than those associated with Machinery, we continue to believe that two capital-related cost categories are appropriate. The resulting proposed 2020-based ESRDB market basket weights for Capital-related

Buildings and Fixtures and Capital-related Moveable Equipment are 9.4 and 4.4 percent, respectively.

Administrative & General

We computed the proportion of total Administrative & General expenditures using the Administrative and General cost center data from Worksheet B, the sum of lines 8 through 17, (column 9) of the MCRs. Additionally, we removed contract labor from this cost category and apportioned these costs to the Wages and Salaries and Employee Benefits cost weights. Similar to other expenditure category adjustments, we then reduced the computed weight to exclude Wages and Salaries and Benefits associated with the Administrative and General cost center for Non-direct Patient Care as estimated from the SAS data. The resulting Administrative and General cost weight is 13.7 percent.

We are proposing to further disaggregate the Administrative and General cost weight to derive detailed cost weights for Electricity, Natural Gas, Telephone, Professional Fees, and All Other Goods and Services. These detailed cost weights were derived by inflating the detailed 2012 SAS data forward to 2020 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2012 SAS data. We repeated this practice for each year to 2020. We then calculated the cost shares that each cost category represents of the 2012 data inflated to 2020. These resulting 2020 cost shares were applied to the Administrative and General cost weight derived from the MCR (net of contract labor and additional benefits) to obtain the detailed cost weights for the proposed 2020-based ESRDB market basket. This method is similar to the method used for the 2016-based ESRDB market basket.

Table 4 lists all of the cost categories and cost weights in the proposed 2020-based ESRDB market basket compared to the 2016-based ESRDB market basket.

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TABLE 4: Comparison of the Proposed 2020-based and the 2016-based ESRDB Market Basket Cost Categories and Weights

Proposed 2020 Cost Category	Proposed 2020 Cost Weights (percent)	2016 Cost Weights (percent)
Total	100.0	**100.0**
Compensation	**45.9**	**43.6**
Wages and Salaries	36.5	34.5
Employee Benefits	9.5	9.1
Utilities	**1.4**	**2.0**
Electricity	1.2	1.1
Natural Gas	0.1	0.1
Water and Sewerage	n/a	0.8
Medical Supplies & Laboratory Services	**22.4**	**24.9**
Pharmaceuticals	10.1	12.4
ESAs	6.0	10.0
Other Drugs (except ESAs)	4.1	2.4
Supplies	11.0	10.4
Laboratory Services	1.3	2.2
All Other Goods and Services	**16.6**	**16.4**
Telephone & Internet Services	0.5	0.5
Housekeeping	0.5	3.9
Operations & Maintenance	3.7	n/a
Professional Fees	0.8	0.7
All Other Goods and Services	11.1	11.3
Capital Costs	**13.8**	**13.0**
Capital Related-Building and Fixtures	9.4	9.2
Capital Related-Machinery	4.4	3.8

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal and, therefore, the detail may not add to the total due to rounding.

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(c) Proposed Price Proxies for the 2020-Based ESRDB Market Basket

After developing the cost weights for the proposed 2020-based ESRDB market basket, we are proposing to select the most appropriate wage and price proxies currently available to represent the rate of price change for each expenditure category. We based the proposed price proxies on BLS data and group them into one of the following BLS categories:

- *Employment Cost Indexes.* Employment Cost Indexes (ECIs) measure the rate of change in employment wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the NAICS and the occupational ECIs are based on the Standard Occupational Classification System (SOC).
- *Producer Price Indexes.* Producer Price Indexes (PPIs) measure price changes for goods sold in other than retail markets. PPIs are used when the purchases of goods or services are made at the wholesale level.
- *Consumer Price Indexes.* Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by consumers. CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the wholesale level, or if no appropriate PPIs are available.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance:

Reliability. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.)

Timeliness. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly, and therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available.

Availability. Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this helps to ensure that our market basket increase factors are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.

Relevance. Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. The CPIs, PPIs, and ECIs that we have selected to propose in this proposed rule meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

Table 7 lists all proposed price proxies for the proposed 2020-based ESRDB market basket. We note that we are proposing to use the same proxies as those used in the 2016-based ESRDB market basket, except for the price proxy for the Other Drugs (except ESAs) cost category. Below is a detailed explanation of the proposed price proxies used for each cost category.

Wages and Salaries

We are proposing to continue using a blend of ECIs to proxy the Wages and Salaries cost weight in the proposed 2020-based ESRDB market basket, and to continue using four occupational categories and associated ECIs based on full-time equivalents (FTE) data from ESRD MCRs and ECIs from BLS. We calculated occupation weights for the blended Wages and Salaries price proxy using 2020 FTE data from the MCR data multiplied by the associated 2020 Average Mean Wage data from the Bureau of Labor Statistics' Occupational Employment Statistics. This is similar to the methodology used in the 2016-based ESRDB market basket to derive these occupational wages and salaries categories.

Health Related Wages and Salaries

We are proposing to continue using the ECI for Wages and Salaries for All Civilian Workers in Hospitals (BLS series code #CIU1026220000000I) as the price proxy for health-related occupations. Of the two health-related ECIs that we considered (''Hospitals'' and ''Health Care and Social Assistance''), the wage distribution within the Hospital NAICS sector (622) is more closely related to the wage distribution of ESRD facilities than it is to the wage distribution of the Health Care and Social Assistance NAICS sector (62).

The Wages and Salaries—Health Related subcategory weight within the Wages and Salaries cost category accounts for 79.4 percent of total Wages and Salaries in 2020. The ESRD MCR FTE categories used to define the Wages and Salaries—Health Related subcategory include ''Physicians,'' ''Registered Nurses,'' ''Licensed Practical Nurses,'' ''Nurses' Aides,'' ''Technicians,'' and ''Dieticians''.

Management Wages and Salaries

We are proposing to continue using the ECI for Wages and Salaries for Private Industry Workers in Management, Business, and Financial (BLS series code #CIU2020000110000I). We believe this ECI is the most appropriate price proxy to measure the wages and salaries price growth of management personnel at ESRD facilities.

The Wages and Salaries—Management subcategory weight within the Wages and Salaries cost category is 9.0 percent in 2020. The ESRD MCR FTE category used to define the Wages and Salaries—Management subcategory is ''Management.''

Administrative Wages and Salaries

We are proposing to continue using the ECI for Wages and Salaries for Private Industry Workers in Office and Administrative Support (BLS series code #CIU2020000220000I). We believe this ECI is the most appropriate price proxy to measure the wages and salaries price growth of administrative support personnel at ESRD facilities.

The Wages and Salaries—Administrative subcategory weight within the Wages and Salaries cost category is 5.3 percent in 2020. The ESRD MCR FTE category used to define the Wages and Salaries—Administrative subcategory is ''Administrative.''

Services Wages and Salaries

We are proposing to continue using the ECI for Wages and Salaries for Private Industry Workers in Service Occupations (BLS series code #CIU2020000300000I). We believe this ECI is the most appropriate price proxy to measure the wages and salaries price growth of all other non-health related, non-management, and non-

administrative service support personnel at ESRD facilities.

The Services subcategory weight within the Wages and Salaries cost category is 6.3 percent in 2020. The ESRD MCR FTE categories used to define the Wages and Salaries—Services subcategory are ''Social Workers'' and ''Other.''

Table 5 lists the four ECI series and the corresponding weights used to construct the proposed ECI blend for Wages and Salaries compared to the 2016-based weights for the subcategories. We believe this proposed ECI blend is the most appropriate price proxy to measure the growth of wages and salaries faced by ESRD facilities.

TABLE 5: Proposed ECI Blend for Wages and Salaries in the Proposed 2020-Based and 2016-Based ESRDB Market Baskets

Cost Category	ECI Series	Proposed 2020 Weight	2016 Weight
Health Related	ECI for Wages and Salaries for All Civilian Workers in Hospitals	79.4%	79.9%
Management	ECI for Wages and Salaries for Private Industry Workers in Management, Business, and Financial	9.0%	6.7%
Administrative	ECI for Wages and Salaries for Private Industry Workers in Office and Administrative Support	5.3%	7.7%
Services	ECI for Wages and Salaries for Private Industry Workers in Service Occupations	6.3%	5.7%

Employee Benefits

We are proposing to continue using an ECI blend for Employee Benefits in the proposed 2020-based ESRDB market basket where the components match those of the proposed Wage and Salaries ECI blend. The proposed occupation weights for the blended Benefits price proxy (Table 6) are the same as those proposed for the wages and salaries price proxy blend as shown in Table 5. BLS does not publish ECI for Benefits price proxies for each Wage and Salary ECI; however, where these series are not published, they can be derived by using the ECI for Total Compensation and the relative importance of wages and salaries with total compensation as published by BLS for each detailed ECI occupational index.

Health Related Benefits

We are proposing to continue using the ECI for Benefits for All Civilian Workers in Hospitals to measure price growth of this subcategory. This is calculated using the ECI for Total Compensation for All Civilian Workers in Hospitals (BLS series code #CIU10162200000000I) and the relative importance of Wages and Salaries within Total Compensation as published by BLS. We believe this constructed ECI series is technically appropriate for the reason stated in the Wages and Salaries price proxy section.

Management Benefits

We are proposing to continue using the ECI for Benefits for Private Industry Workers in Management, Business, and Financial to measure price growth of this subcategory. This ECI is calculated using the ECI for Total Compensation for Private Industry Workers in Management, Business, and Financial (BLS series code #CIU20100001100000I) and the relative importance of wages and salaries within total compensation. We believe this constructed ECI series is technically appropriate for the reason stated in the Wages and Salaries price proxy section.

Administrative Benefits

We are proposing to continue using the ECI for Benefits for Private Industry Workers in Office and Administrative Support to measure price growth of this subcategory. This ECI is calculated using the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code #CIU2010000220000I) and the relative importance of Wages and Salaries within Total Compensation. We believe this constructed ECI series is technically appropriate for the reason stated in the wages and salaries price proxy section.

Services Benefits

We are proposing to continue using the ECI for Total Benefits for Private Industry Workers in Service Occupations (BLS series code #CIU2030000300000I) to measure price growth of this subcategory. We believe this ECI series is technically appropriate for the reason stated in the Wages and Salaries price proxy section. We believe the proposed benefits ECI blend continues to be the most appropriate price proxy to measure the growth of benefits prices faced by ESRD facilities. Table 6 lists the four ECI series and the corresponding weights used to construct the proposed benefits ECI blend.

TABLE 6: Proposed ECI Blend for Benefits in the Proposed 2020-Based and 2016-Based ESRDB Market Baskets

Cost Category	ECI Series	Proposed 2020 Weight	2016 Weight
Health Related	ECI for Benefits for All Civilian Workers in Hospitals.	79.4%	79.9%
Management	ECI for Benefits for Private Industry Workers in Management, Business, and Financial.	9.0%	6.7%
Administrative	ECI for Benefits for Private Industry Workers in Office and Administrative Support.	5.3%	7.7%
Services	ECI for Benefits for Private Industry Workers in Service Occupations.	6.3%	5.7%

Electricity

We are proposing to continue using the PPI Commodity for Commercial Electric Power (BLS series code #WPU0542) to measure the price growth of this cost category.

Natural Gas

We are proposing to continue using the PPI Commodity for Commercial Natural Gas (BLS series code #WPU0552) to measure the price growth of this cost category.

Pharmaceuticals

ESAs: We are proposing to continue using the PPI Commodity for Biological Products, Excluding Diagnostic, for Human Use (which we will abbreviate as PPI–BPHU) (BLS series code #WPU063719) as the price proxy for the ESA drugs in the market basket. The PPI–BPHU measures the price change of prescription biologics, and ESAs would be captured within this index, if they are included in the PPI sample. Since the PPI relies on confidentiality with respect to the companies and drugs/biologicals included in the sample, we do not know if these drugs are indeed reflected in this price index. However, we believe the PPI–BPHU is an appropriate proxy to use because although ESAs may be a small part of the fuller category of biological products, we can examine whether the price increases for the ESA drugs are similar to the drugs included in the PPI–BPHU. We did this by comparing the historical price changes in the PPI–BPHU and the average sales price (ASP) for ESAs and found the cumulative growth to be consistent over the past 4 years. We would continue to monitor the trends in the prices for ESA drugs as measured by other price data sources to ensure that the PPI–BPHU is still an appropriate price proxy.

Other Drugs (except ESA): For all other drugs included in the ESRD PPS bundled payment other than ESAs, we are proposing to use a blend of 50 percent of the PPI Commodity for Vitamin, Nutrient, and Hematinic Preparations (which we will abbreviate as PPI–VNHP) (BLS series code #WPU063807), and 50 percent of the PPI Commodity for Pharmaceuticals for human use, prescription (which we will abbreviate as PPI-Pharmaceuticals) (BLS series code #WPUSI07003). We continue to believe that the PPI–VNHP is an appropriate price proxy for the iron supplements commonly used in the treatment of ESRD, and an analysis of claims data indicate that iron supplement costs account for about half of the All Other ESRD-related Drugs costs. For the remaining drugs represented in the non-ESA drug category (such as calcimimetics and Vitamin D analogs) we believe a different price proxy would be more appropriate and we are proposing to use the PPI Commodity for Pharmaceuticals for human use, prescription, which captures the inflationary price pressures for all types of prescription drugs rather than a single therapeutic category of drugs. Though this PPI measure includes a wide variety of prescription drugs, we believe it is technically appropriate to use a broad indicator of prescription drug price trends for three key reasons: (1) the more detailed PPI measure where we believe these types of non-ESA drugs would be captured would more likely reflect price trends not faced by ESRD facilities, such as cancer drugs, (2) there have been notable changes to the types and mix of drugs paid for under the ESRD PPS bundled payment since 2016, such as the inclusion of formerly oral-only calcimimetics and the addition of AKI-related drugs, and (3) the potential for future changes to the types and mix of drugs that may be paid for under the ESRD PPS bundled payment, such as when other drugs that are currently oral-only drugs are included in the ESRD PPS beginning for CY 2025. For these reasons, we believe that a broader drug index representing a larger mix of prescription drugs is a technical improvement to the proposed price proxy for this cost category. We will continue to monitor the relative share of expenses for iron supplements and other types of drugs for this cost category to determine if the proposed 50/50 PPI blend warrants an adjustment, and if so, we would propose such an adjustment in future rulemaking.

Supplies

We are proposing to continue using the PPI Commodity for Surgical and Medical Instruments (BLS series code #WPU1562) to measure the price growth of this cost category.

Laboratory Services

We are proposing to continue using the PPI Industry for Medical Laboratories (BLS series code #PCU621511621511) to measure the price growth of this cost category.

Telephone Service

We are proposing to continue using the CPI U.S. city average for Telephone Services (BLS series code #CUUR0000SEED) to measure the price growth of this cost category.

Housekeeping

We are proposing to continue using the PPI Commodity for Cleaning and Building Maintenance Services (BLS series code #WPU49) to measure the price growth of this cost category.

Operations & Maintenance

For the Operations & Maintenance cost category, we are proposing to use the ECI for Total compensation for All Civilian workers in Installation, maintenance, and repair (BLS series code #CIU10100004300001) to measure the price growth of this cost category.

This price proxy accounts for the compensation expenses related to maintenance and repair workers. We believe the majority of expenses for maintenance and repair to be labor-related costs and therefore, believe that this ECI is the most technically appropriate price proxy for this cost category.

Professional Fees

We are proposing to continue using the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code #CIU2010000120000I) to measure the price growth of this cost category.

All Other Goods and Services

We are proposing to continue using the PPI Commodity for Final demand—Finished Goods Less Foods and Energy (BLS series code #WPUFD4131) to measure the price growth of this cost category.

Capital-Related Building and Fixtures

We are proposing to continue using the PPI Industry for Lessors of Nonresidential Buildings (BLS series code #PCU531120531120) to measure the price growth of this cost category.

Capital-Related Moveable Equipment

We are proposing to continue using the PPI Commodity for Electrical Machinery and Equipment (BLS series code #WPU117) to measure the price growth of this cost category.

Table 7 shows all the proposed price proxies and cost weights for the proposed 2020-based ESRDB Market Basket.

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TABLE 7: Proposed Price Proxies and associated Cost Weights for the 2020-based ESRDB Market Basket

Cost Category	Price Proxy	Proposed 2020 Cost Weight
Total ESRDB Market Basket		100.0%
Compensation		**45.9%**
Wages and Salaries		36.5%
Health-related	ECI for Wages and Salaries for All Civilian Workers in Hospitals.	28.9%
Management	ECI for Wages and Salaries for Private Industry Workers in Management, Business, and Financial.	3.3%
Administrative	ECI for Wages and Salaries for Private Industry Workers in Office and Administrative Support.	1.9%
Services	ECI for Wages and Salaries for Private Industry Workers in Service Occupations.	2.3%
Employee Benefits		9.5%
Health-related	ECI for Total Benefits for All Civilian workers in Hospitals.	7.5%
Management	ECI for Total Benefits for Private Industry workers in Management, Business, and Financial.	0.9%
Administrative	ECI for Total Benefits for Private Industry workers in Office and Administrative Support.	0.5%
Services	ECI for Total Benefits for Private Industry workers in Service Occupations.	0.6%
Utilities		**1.4%**
Electricity	PPI Commodity for Commercial Electric Power.	1.2%
Natural Gas	PPI Commodity for Commercial Natural Gas.	0.1%
Medical Materials and Supplies		**22.4%**
Pharmaceuticals		10.1%
ESAs	PPI Commodity for Biological Products, Excluding Diagnostics, for Human Use.	6.0%
Other Drugs	50/50 blend of the PPI Commodity for Vitamin, Nutrient, and Hematinic Preparations, and the PPI Commodity for Pharmaceuticals for human use, prescription	4.1%
Supplies	PPI Commodity for Surgical and Medical Instruments.	11.0%
Laboratory Services	PPI Industry for Medical Laboratories.	1.3%
All Other Goods and Services		**16.6%**
Telephone Service	CPI-U for Telephone Services.	0.5%
Housekeeping	PPI Commodity for Cleaning and Building Maintenance Services.	0.5%
Operations & Maintenance	ECI for Total compensation for All Civilian workers in Installation, maintenance, and repair	3.7%
Professional Fees	ECI for Total Compensation for Private Industry Workers in Professional and Related.	0.8%
All Other Goods and Services	PPI for Final demand - Finished Goods less Foods and Energy.	11.1%
Capital Costs		**13.8%**
Capital Related Building and Fixtures	PPI Industry for Lessors of Nonresidential Buildings.	9.4%
Capital Related Moveable Equipment	PPI Commodity for Electrical Machinery and Equipment.	4.4%

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal and therefore, the detail may not add to the total due to rounding.

(d) Proposed Rebasing Results

A comparison of the yearly differences of increase factors from CY 2019 to CY 2023 for the 2016-based ESRDB market basket and the proposed 2020-based ESRDB market basket is shown in Table 8. The CY 2023 ESRDB market basket increase factor would be 0.2 percentage point lower if we continued to use the 2016-based ESRDB market basket. For the years prior to CY 2023 the annual market basket increase factors were the same, except for CY 2021 where the proposed 2020-based market basket was 0.1 percentage point lower.

TABLE 8: Historical and Projected Market Basket Increase Factors under the Proposed 2020-based ESRDB Market Basket and 2016-based ESRDB Market Basket

Calendar Year (CY)	Proposed 2020-based ESRDB Market Basket	2016-based ESRDB Market Basket	Proposed 2020-based ESRDB Market Basket less 2016-based ESRDB Market Basket
Historical Data:			
CY 2019	2.3	2.3	0.0
CY 2020	1.9	1.9	0.0
CY 2021	3.0	3.1	-0.1
Forecast:			
CY 2022	4.5	4.5	0.0
CY 2023	2.8	2.6	0.2

Source: IHS Global Inc. 1st quarter 2022 forecast with historical data through 4th quarter 2021

(2) Proposed Labor-Related Share for ESRD PPS

We define the labor-related share (LRS) as those expenses that are labor-intensive and vary with, or are influenced by, the local labor market. The labor-related share of a market basket is determined by identifying the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market.

We are proposing to use the proposed 2020-based ESRDB market basket cost weights to determine the proposed labor-related share for ESRD facilities. Therefore, effective for CY 2023, we are proposing a labor-related share of 55.2 percent, compared to the current 52.3 percent that was based on the 2016-based ESRDB market basket, as shown in Table 9. These figures represent the sum of Wages and Salaries, Benefits, Housekeeping, Operations & Maintenance, 87 percent of the weight for Professional Fees (details discussed later in this subsection), and 46 percent of the weight for Capital-related Building and Fixtures expenses (details discussed later in this subsection). We used the same methodology for the 2016-based ESRDB market basket.

TABLE 9: Labor-Related Share of Current and Proposed ESRD Bundled Market Baskets

Cost Category	Proposed 2020-based ESRDB Market Basket Weights	2016-based ESRDB Market Basket Weights
Wages and Salaries	36.5	34.5
Employee Benefits	9.5	9.1
Housekeeping*	0.5	3.9
Operations & Maintenance	3.7	n/a
Professional Fees (Labor-Related)	0.7	0.6
Capital Labor-Related	4.3	4.2
Total Labor-Related Share	55.2	52.3

*The 2016-based ESRDB labor-related share had a combined category weight for Housekeeping and Operations

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The proposed labor-related share for Professional Fees reflects the proportion of ESRD facilities' professional fees expenses that we believe vary with local labor market (87 percent). We conducted a survey of ESRD facilities in 2008 to better understand the proportion of contracted professional

services that ESRD facilities typically purchase outside of their local labor market. These purchased professional services include functions such as accounting and auditing, management consulting, engineering, and legal services. Based on the survey results, we determined that, on average, 87 percent of professional services are purchased from local firms and 13 percent are purchased from businesses located outside of the ESRD's local labor market. Thus, we are proposing to include 87 percent of the cost weight for Professional Fees in the labor-related share (87 percent is the same percentage as used in prior years).

The proposed labor-related share for capital-related expenses reflects the proportion of ESRD facilities' capital-related expenses that we believe varies with local labor market wages (46 percent of ESRD facilities' Capital-related Building and Fixtures expenses). Capital-related expenses are affected in some proportion by variations in local labor market costs (such as construction worker wages) that are reflected in the price of the capital asset. However, many other inputs that determine capital costs are not related to local labor market costs, such as interest rates. The 46-percent figure is based on regressions run for the inpatient hospital capital PPS in 1991 (56 FR 43375). We use a similar methodology to calculate capital-related expenses for the labor-related shares for rehabilitation facilities (70 FR 30233), psychiatric facilities, long-term care facilities, and skilled nursing facilities (66 FR 39585).

(3) Proposed CY 2023 ESRD Market Basket Increase Factor, Adjusted for Productivity

Under section 1881(b)(14)(F)(i) of the Act, beginning in CY 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket percentage increase factor and reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. We are proposing to use the 2020-based ESRDB market basket as described in section II.B.1 of this proposed rule to compute the CY 2023 ESRDB market basket increase factor and labor-related share based on the best available data. Consistent with historical practice, we propose to estimate the ESRDB market basket increase factor based on IHS Global Inc.'s (IGI) forecast using the most recently available data. IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets.

(a) Proposed CY 2023 Market Basket Increase Factor

Using this methodology and the IGI forecast available in the first quarter of 2022 of the proposed 2020-based ESRDB market basket (with historical data through the fourth quarter of 2021), and consistent with our historical practice of estimating market basket increases based on the best available data, the proposed CY 2023 ESRDB market basket increase factor is 2.8 percent.

(b) Proposed Productivity Adjustment

Under section 1881(b)(14)(F)(i) of the Act, as amended by section 3401(h) of the Affordable Care Act, for CY 2012 and each subsequent year, the ESRD market basket percentage increase factor shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period) (the ''productivity adjustment''). MFP is derived by subtracting the contribution of labor and capital input growth from output growth. The detailed methodology for deriving the MFP projection was finalized in the CY 2012 ESRD PPS final rule (76 FR 70232 through 70235).

BLS publishes the official measures of productivity for the U.S. economy. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act was published by BLS as private nonfarm business MFP. Beginning with the November 18, 2021 release of productivity data, BLS replaced the term ''multifactor productivity'' with ''total factor productivity'' (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology.[1] As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as private nonfarm business TFP; however, as mentioned previously, the data and methods are unchanged. We refer readers to *https://www.bls.gov/productivity/* for the BLS historical published TFP data. A complete description of IGI's TFP projection methodology is available on the CMS website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.* In addition, in the CY 2022 ESRD PPS final rule (86 FR 61879), we noted that effective for CY 2022 and future years, CMS would be changing the name of this adjustment to refer to it as the productivity adjustment rather than the MFP adjustment. We stated this was not a change in policy, as we will continue to use the same methodology for deriving the adjustment and rely on the same underlying data.

Using this methodology and IGI's first quarter 2022 forecast, the proposed productivity adjustment for CY 2023 (the 10-year moving average of TFP for the period ending CY 2023) is projected to be 0.4 percentage point.

(c) Proposed CY 2023 Market Basket Increase Factor Adjusted for Productivity

As a result of these provisions, the proposed CY 2023 ESRD market basket increase factor reduced by the productivity adjustment is 2.4 percent. This proposed market basket increase factor is calculated by starting with the proposed 2020-based ESRDB market basket percentage increase factor of 2.8 percent for CY 2023, and reducing it by the proposed productivity adjustment (the 10-year moving average of TFP for the period ending CY 2023) of 0.4 percentage point. As is our general practice, we are also proposing that if more recent data are subsequently available (for example, a more recent estimate of the market basket increase factor or productivity adjustment), we would use such data to determine the market basket increase factor and productivity adjustment in the CY 2023 ESRD PPS final rule.

b. Proposed CY 2023 ESRD PPS Wage Indices

(1) Background

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. In the CY 2011 ESRD PPS final rule (75 FR 49200), we finalized an adjustment for wages at § 413.231. Specifically, CMS adjusts the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index, which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. We use OMB's CBSA-based

[1] Total Factor Productivity in Major Industries—2020. Available at: *https://www.bls.gov/news.release/prod5.nr0.htm.*

geographic area designations to define urban and rural areas and their corresponding wage index values (75 FR 49117). OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. The bulletins are available online at *https://www.whitehouse.gov/omb/information-for-agencies/bulletins/.*

For CY 2023, we are proposing to update the wage indices to account for updated wage levels in areas in which ESRD facilities are located using our existing methodology. We use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient PPS. The ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Act and utilize prefloor hospital data that are unadjusted for occupational mix. For CY 2023, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2018, and before October 1, 2019 (FY 2019 cost report data).

We have also adopted methodologies for calculating wage index values for ESRD facilities that are located in urban and rural areas where there is no hospital data. For a full discussion, see the CY 2011 and CY 2012 ESRD PPS final rules at 75 FR 49116 through 49117 and 76 FR 70239 through 70241, respectively. For urban areas with no hospital data, we compute the average wage index value of all urban areas within the state to serve as a reasonable proxy for the wage index of that urban CBSA, that is, we use that value as the wage index. For rural areas with no hospital data, we compute the wage index using the average wage index values from all contiguous CBSAs to represent a reasonable proxy for that rural area. We apply the statewide urban average based on the average of all urban areas within the state to Hinesville-Fort Stewart, Georgia (78 FR 72173), and we apply the wage index for Guam to American Samoa and the Northern Mariana Islands (78 FR 72172).

A wage index floor value (0.5000) is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values. Currently, all areas with wage index values that fall below the floor are located in Puerto Rico. However, the wage index floor value is applicable for any area that may fall below the floor. A description of the history of the wage index floor under the ESRD PPS can be found in the CY 2019 ESRD PPS final rule (83 FR 56964 through 56967).

An ESRD facility's wage index is applied to the labor-related share of the ESRD PPS base rate. In the CY 2019 ESRD PPS final rule (83 FR 56963), we finalized a labor-related share of 52.3 percent, which was based on the 2016-based ESRDB market basket. In the CY 2021 ESRD PPS final rule (85 FR 71436), we updated the OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, beginning with the CY 2021 ESRD PPS wage index. In addition, we finalized the application of a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior CY. We finalized that the transition would be phased in over 2 years, such that the reduction in an ESRD facility's wage index would be capped at 5 percent in CY 2021, and no cap would be applied to the reduction in the wage index for the second year, CY 2022. For CY 2023, as discussed in section II.B.1.a (2) of this proposed rule, the proposed labor-related share to which the wage index would be applied is 55.2 percent, based on the proposed 2020-based ESRDB market basket.

For CY 2023, we are proposing to update the ESRD PPS wage index to use the most recent hospital wage data. The proposed CY 2023 ESRD PPS wage index is set forth in Addendum A and is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.* Addendum A provides a crosswalk between the CY 2022 wage index and the proposed CY 2023 wage index. Addendum B provides an ESRD facility level impact analysis. Addendum B is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.*

(2) Proposed Permanent Cap on Wage Index Decreases

As discussed in section II.B.1.b(1) of this proposed rule and in previous ESRD PPS rules, under the authority of section 1881(b)(14)(D)(iv)(II) of the Act, we have proposed and finalized temporary, budget-neutral transition policies in the past to help mitigate negative impacts on ESRD facilities following the adoption of certain ESRD PPS wage index changes. In the CY 2015 ESRD PPS final rule (79 FR 66142), we implemented revised OMB area delineations using a 2-year transition, with a 50/50 blended wage index for all ESRD facilities in CY 2015 [2] and 100 percent of the wage index based on the new OMB delineations in CY 2016. In the CY 2021 ESRD PPS proposed rule (85 FR 42160 through 42161), we proposed a transition policy to help mitigate any negative impacts that ESRD facilities may experience due to our proposal to adopt the 2018 OMB delineations under the ESRD PPS. We noted that because the overall amount of ESRD PPS payments would increase slightly due to the 2018 OMB delineations, the effect of the wage index budget neutrality factor would be to reduce the ESRD PPS per treatment base rate for all ESRD facilities paid under the ESRD PPS, despite the fact that the majority of ESRD facilities would be unaffected by the 2018 OMB delineations. Thus, we explained that we believed it would be appropriate to provide for a transition period to mitigate the resulting short-term instability of a lower ESRD PPS base rate as well as consequential negative impacts to ESRD facilities that experience reduced payments. We proposed to apply a 5-percent cap on any decrease in an ESRD facility's wage index from its final wage index from the prior calendar year, that is, CY 2020. We explained that we believed the 5-percent cap would provide greater transparency and would be administratively less complex than the prior methodology of applying a 50/50 blended wage index (85 FR 71478). We proposed that no cap would be applied to the reduction in the wage index for the second year, that is, CY 2022 (85 FR 42161).

Several commenters to the CY 2021 ESRD PPS proposed rule supported the wage index transition policy that we proposed for CY 2021; however, as discussed in the CY 2021 ESRD PPS final rule (86 FR 71434 through 71436), some commenters expressed concerns about the large negative effects of the new labor market area delineations on certain areas. A patient organization suggested that the 5 percent cap may not provide an adequate transition for labor market areas that would experience a decrease in their wage index of greater than 10 percent. Similarly, a national non-profit dialysis organization recommended that CMS provide an extended transition period, beyond the proposed 5 percent limit for 2021, for at least 3 years. Some commenters, including MedPAC, suggested

[2] ESRD facilities received 50 percent of their CY 2015 wage index value based on the OMB delineations for CY 2014 and 50 percent of their CY 2015 wage index value based on the newer OMB delineations. 79 FR 66142.

alternatives to the methodology. MedPAC suggested that the 5 percent cap limit should apply to both increases and decreases in the wage index.

We stated in the CY 2021 ESRD PPS final rule that we believed a 5 percent cap on the overall decrease in an ESRD facility's wage index value would be an appropriate transition, as it would effectively mitigate any significant decreases in an ESRD facility's wage index for CY 2021. With respect to extending the transition period for at least 3 years, we stated that we believed this would undermine the goal of the wage index policy, which is to improve the accuracy of payments under the ESRD PPS, and would serve to further delay improving the accuracy of the ESRD PPS by continuing to pay certain ESRD facilities more than their wage data suggest is appropriate. We also stated that the transition policies are not intended to curtail the positive impacts of certain wage index changes, so it would not be appropriate to also apply the 5 percent cap on wage index increases. We acknowledged that a transition policy was necessary to help mitigate initial significant negative impacts from revised OMB delineations, but expressed that this mitigation must be balanced against the importance of ensuring accurate payments. We finalized the transition policy for CY 2021 as proposed. We did not propose to extend the transition policy for CY 2022 or future years, however, as we discussed in the CY 2022 ESRD PPS final rule (86 FR 61881), we received comments acknowledging and supporting the final phase-in of the updated OMB delineations for CY 2022.

Based on our past wage index transition policies and public comments, we recognize that certain changes to our wage index policy may significantly affect Medicare payments to ESRD facilities. Commenters have raised concerns about scenarios in which changes to wage index policy may have significant negative impacts on ESRD facilities. Therefore, we considered for this CY 2023 ESRD PPS proposed rule how best to address those scenarios.

In the past, we have established transition policies of limited duration to phase in significant changes to labor market areas, such as revised OMB delineations. In taking this approach in the past, we sought to mitigate short-term instability and fluctuations that can negatively impact ESRD facilities due to wage index changes. In accordance with the ESRD PPS wage index regulations at § 413.231(a), we adjust the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index that is established by CMS, and which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. Our policy is generally to use the most current hospital wage data and analysis available in order to ensure the accuracy of the ESRD PPS wage index, in accordance with § 413.196(d)(2). As discussed earlier in this section of the proposed rule, we believe that past wage index transition policies have helped mitigate initial significant negative impacts from changes such as revised OMB delineations. However, we recognize that changes to the wage index have the potential to create instability and significant negative impacts on certain ESRD facilities even when labor market areas do not change as a result of revised OMB delineations. In addition, year-to-year fluctuations in an area's wage index can occur due to external factors beyond an ESRD facility's control, such as the COVID–19 PHE, and for an individual ESRD facility, these fluctuations can be difficult to predict. While we have maintained that temporary transition policies provide sufficient time for facilities to make operational changes for future CYs and have noted separate agency actions to address certain external factors, such as the issuance of waivers and flexibilities during the COVID–19 PHE (85 FR 71435), we also recognize that predictability in Medicare payments is important to enable ESRD facilities to budget and plan their operations.

In light of these considerations, we are proposing a permanent mitigation policy to smooth the impact of year-to-year changes in ESRD PPS payments related to decreases in the ESRD PPS wage index. We are proposing a policy that we believe would increase the predictability of ESRD PPS payments for ESRD facilities; mitigate instability and significant negative impacts to ESRD facilities resulting from changes to the wage index; and use the most current data to maintain the accuracy of the ESRD PPS wage index.

As previously discussed, we believe our transition policy that applied a 5-percent cap on wage index decreases for CY 2021 provided greater transparency and was administratively less complex than prior transition methodologies. In addition, we believe this methodology mitigated short-term instability and fluctuations that can negatively impact ESRD facilities due to wage index changes. Lastly, we believe the 5-percent cap we applied to all wage index decreases for CY 2021 provided an adequate safeguard against significant and unpredictable payment reductions in that year, related to the adoption of the revised OMB delineations. However, as discussed earlier in this section of the proposed rule, we recognize there are circumstances that a 2-year transition policy, like the one adopted for CY 2021, would not effectively address for future years in which ESRD facilities continue to be negatively affected by significant wage index decreases. We believe our proposed permanent policy would eliminate the need for temporary and potentially uncertain transition adjustments to the wage index in the future due to specific policy changes or circumstances outside ESRD facilities' control (for example, public health or other emergencies, or the adoption of future OMB revisions to the CBSA delineations through rulemaking).

Typical year-to-year variation in the ESRD PPS wage index has historically been within 5 percent, and we expect this will continue to be the case in future years. Because ESRD facilities are usually experienced with this level of wage index fluctuation, we believe applying a 5-percent cap on all wage index decreases each year, regardless of the reason for the decrease, would effectively mitigate instability in ESRD PPS payments due to any significant wage index decreases that may affect ESRD facilities in a year. Therefore, we believe this approach would address concerns about instability that commenters raised in response to the CY 2021 ESRD PPS proposed rule. In addition, we believe that applying a 5-percent cap on all wage index decreases would support increased predictability about ESRD PPS payments for ESRD facilities, enabling them to more effectively budget and plan their operations. Lastly, because applying a 5-percent cap on all wage index decreases would represent a small overall impact on the labor market area wage index system, we believe it would still ensure the wage index is a relative measure of the value of labor in prescribed labor market areas. With a permanent cap, we would be able to continue to update the wage index with the most current hospital wage data as required under § 413.196(d)(2) in order to more accurately align the use of labor resources with ESRD PPS payment while mitigating the instability in payments to individual ESRD facilities that such updates may otherwise cause. As discussed in section II.B.1.d(2) of this proposed rule, we compute a wage index budget-neutrality adjustment factor that is applied to the ESRD PPS

base rate. As discussed in further detail in that section, we estimate that applying a 5-percent cap on all wage index decreases would have a very small effect on the wage index budget neutrality factor for CY 2023, and therefore would have a small effect on the ESRD PPS base rate. This small effect on budget neutrality also demonstrates that this policy would have a minimal impact on the ESRD PPS wage index overall. The wage index [3] is a measure of the value of labor (wage and wage-related costs) in a prescribed labor market area relative to the national average. Therefore, we anticipate that in the absence of any proposed wage index policy changes such as changes to OMB delineations, most ESRD facilities would not experience year-to-year wage index declines greater than 5 percent in any given year. Therefore, we anticipate that the impact to the wage index budget neutrality factor in future years would continue to be minimal. We also believe that when the 5-percent cap would be applied under this proposed policy, it likely would be applied similarly to all ESRD facilities in the same labor market area, as the hospital average hourly wage data in the CBSA (and any relative decreases compared to the national average hourly wage) would be similar. While this proposed policy may result in ESRD facilities in a CBSA receiving a higher wage index than others in the same area (such as in situations when OMB delineations change), we believe the impact would be temporary, as the average hourly wage of facilities in a labor market would tend to converge to the mean average hourly wage of the CBSA.

As noted previously in this section of the proposed rule, section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. Under our regulations at § 413.231(a), we must use an appropriate wage index to adjust the labor-related portion of the base rate to account for geographic differences in the area wage levels. For the reasons discussed in this section of the proposed rule, we believe a 5-percent cap on wage index decreases would be appropriate for the ESRD PPS. Therefore, for CY 2023 and subsequent years, we are proposing to apply a 5-percent cap on any decrease to an ESRD facility's wage index from its wage index in the prior year, regardless of the circumstances causing the decline. That is, we are proposing that an ESRD facility's wage index for CY 2023 would not be less than 95 percent of its final wage index for CY 2022, regardless of whether the ESRD facility is part of an updated CBSA, and that for subsequent years, an ESRD facility's wage index would not be less than 95 percent of its wage index calculated in the prior CY. This also would mean that if an ESRD facility's prior CY wage index is calculated with the application of the 5-percent cap, the following year's wage index would not be less than 95 percent of the ESRD facility's capped wage index in the prior CY. For example, if an ESRD facility's wage index for CY 2023 is calculated with the application of the 5-percent cap, then its wage index for CY 2024 would not be less than 95 percent of its capped wage index in CY 2023. Lastly, we are proposing that a newly opened or newly certified ESRD facility would be paid the wage index for the area in which it is geographically located for its first full or partial CY with no cap applied, because a new ESRD facility would not have a wage index in the prior CY. We would reflect the proposed permanent cap on wage index decreases in our regulations at § 413.231(c).

As previously discussed in this proposed rule, we believe this proposed mitigation policy would maintain the ESRD PPS wage index as a relative measure of the value of labor in prescribed labor market areas, increase predictability of ESRD PPS payments for ESRD facilities, and mitigate instability and significant negative impacts to ESRD facilities resulting from significant changes to the wage index. In section VII.D.5 of this proposed rule, we estimate the impact to payments for ESRD facilities in CY 2023 based on this proposed policy. We also note that we would examine the effects of this proposed policy, if finalized, on an ongoing basis in the future in order to assess its continued appropriateness.

(3) Proposed Update to ESRD PPS Wage Index Floor

(a) Background

A wage index floor value is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values. Currently, all areas with wage index values that fall below the floor are located in Puerto Rico; however, the wage index floor value is applicable for any area that may fall below the floor.

In the CY 2011 ESRD PPS final rule (75 FR 49116 through 49117), we finalized a policy to reduce the wage index floor by 0.05 for each of the remaining years of the ESRD PPS transition, that is, until CY 2014. We applied a 0.05 reduction to the wage index floor for CYs 2012 and 2013, resulting in a wage index floor of 0.5500 and 0.5000, respectively (CY 2012 ESRD PPS final rule, 76 FR 70241). We continued to apply and reduce the wage index floor by 0.05 in CY 2013 (77 FR 67459 through 67461). Although we only intended to provide a wage index floor during the 4-year transition in the CY 2014 ESRD PPS final rule (78 FR 72173), we decided to continue to apply the wage index floor and reduce it by 0.05 per year for CY 2014 and for CY 2015, resulting in a wage index floor of 0.4500 and 0.4000, respectively.

In the CY 2016 ESRD PPS final rule (80 FR 69006 through 69008), however, we decided to maintain a wage index floor of 0.4000, rather than further reduce the floor by 0.05. We stated that we needed more time to study the wage indices that are reported for Puerto Rico to assess the appropriateness of discontinuing the wage index floor (80 FR 69006).

In the CY 2017 ESRD PPS proposed rule (81 FR 42817), we presented the findings from analyses of ESRD facility cost report and claims data submitted by facilities located in Puerto Rico and mainland facilities. We solicited public comments on the wage index for CBSAs in Puerto Rico as part of our continuing effort to determine an appropriate policy. We did not propose to change the wage index floor for CBSAs in Puerto Rico, but we requested public comments in which interested parties could provide useful input for consideration in future decision making. Specifically, we solicited comment on the suggestions that were submitted in the CY 2016 ESRD PPS final rule (80 FR 69007). After considering the public comments we received regarding the wage index floor, in the CY 2017 ESRD PPS final rule, we finalized a wage index floor of 0.4000 (81 FR 77858).

In the CY 2018 ESRD PPS final rule (82 FR 50747), we finalized a policy to permanently maintain the wage index floor of 0.4000, because we believed it was set at an appropriate level to provide additional payment support to the lowest wage areas. This policy also obviated the need for an additional budget-neutrality adjustment that would reduce the ESRD PPS base rate, beyond the adjustment needed to reflect updated hospital wage data, in order to

[3] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/wageindex#:~:text=A%20labor%20market%20area's%20wage,portion%20of%20the%20standardized%20amounts.*

maintain budget neutrality for wage index updates.

In the CY 2019 ESRD PPS proposed rule (83 FR 34328 through 34330), we proposed to increase the wage index floor from 0.4000 to 0.5000. We conducted various analyses to support our proposal to increase the wage index floor from 0.4000 to 0.5000. We calculated alternative wage indexes for Puerto Rico that combined labor quantities, that is FTEs, from cost reports with BLS wage information to create two regular Laspeyres price indexes [4] (ranging between 0.510 and 0.550). We discuss this analysis in detail in the following paragraphs, however, the complete discussion can be found in the CY 2019 ESRD PPS proposed rule at 83 FR 34328 through 34330.

In response to the CY 2019 wage index floor proposal, we received several comments. One commenter opposed the proposal and expressed concern over the data sources used to develop the wage indexes in general. This commenter requested additional documentation of our analysis to determine the two alternative wage indices for Puerto Rico. Several commenters expressed support for the proposal to increase the wage index from 0.40 in 2018 to 0.50 for CY 2019 and subsequent years, because they believed it would assist ESRD facilities in providing access to high-quality care particularly in rural areas where access challenges may be present. Some commenters expressed support for CMS's position that the then-current wage index floor was too low; however, they recommended CMS set the wage index floor higher than 0.5000 (specifically, at 0.5936, which was identified as the lower boundary of CMS's statistical outlier analysis as discussed further in this section of the proposed rule).

In response to these comments, in the CY 2019 ESRD PPS final rule (83 FR 56967), we stated that we continued to believe that a wage index floor of 0.5000 struck an appropriate balance between providing additional payments to areas that fell below the wage floor while minimizing the impact on the ESRD PPS base rate. We noted that the purpose of the wage index adjustment is to recognize differences in ESRD facility resource use for wages specific to the geographic area in which facilities are located. While a wage index floor of 0.5000 continued to be the lowest wage index nationwide, we noted that the areas subject to the floor continued to have the lowest wages compared to mainland facilities. We noted that the increase to the wage index floor to 0.5000 was a 25 percent increase over the then-current floor and would provide a higher wage index for all facilities in Puerto Rico where wage indexes, based on hospital reported data, range from .3300 to .4400. For these reasons, we stated that we believed a wage index floor of 0.5000 was appropriate and would support labor costs in low wage areas.

Therefore, in the CY 2019 ESRD PPS final rule (83 FR 56964 through 56967), we finalized an increase to the wage index floor from 0.4000 to 0.5000 for CY 2019 and subsequent years. We explained that we revisited our evaluation of payments to ESRD facilities located in the lowest wage areas to be responsive to comments from interested parties and to ensure payments under the ESRD PPS are appropriate. We provided statistical analyses that supported a higher wage index floor and finalized an increase from 0.4000 to 0.5000 to safeguard access to care in affected areas.

As noted previously in this proposed rule, currently, all areas with wage index values that fall below the floor are located in Puerto Rico; however, the wage index floor value is applicable for any area that may fall below the floor. The wage index floor of 0.5000 has been in effect since January 1, 2019.

We did not include any wage index floor proposals in the CY 2022 ESRD PPS proposed rule, however, we received several public comments regarding the wage index floor. As discussed in the CY 2022 ESRD PPS final rule (86 FR 61881), three commenters, including a large dialysis organization, a non-profit health insurance organization in Puerto Rico, and a healthcare group in Puerto Rico, commented on the wage index for ESRD facilities located in Puerto Rico. These commenters recommended that CMS increase the wage index floor from 0.5000 to 0.5500, noting that in the CY 2019 ESRD PPS proposed rule, CMS reported that its own analysis indicated that Puerto Rico's wage index likely lies between 0.5100 and 0.5500. They noted that CMS further stated that any wage index values less than 0.5936 are considered outlier values. They also pointed out that CMS still finalized a floor at 0.5000 and that we characterized it as a balance between providing additional payments to affected areas while minimizing the impact on the ESRD PPS base rate. Another commenter recommended that CMS evaluate policy inequities between the ESRD PPS wage index for ESRD facilities located in Puerto Rico compared to other states and territories, taking into consideration the unique circumstances that affect Puerto Rico, including its shortage of healthcare specialists and labor work force, remote geography, transportation and freighting costs, drug pricing, and lack of transitional care services.

In response to these comments, we stated in the CY 2022 ESRD PPS final rule that we would not finalize any changes to those policies since we did not propose any changes to the wage index floor or wage index methodology for CY 2022, but would take these suggestions into account when considering future rulemaking.

(b) Wage Index Floor Proposal

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. Based on this authority, we believe a proposal to increase the wage index floor would be in accordance with the Secretary's efforts to account for geographic differences in an area's wage levels using an appropriate wage index which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located.

For CY 2023 and subsequent years, we are proposing to increase the wage index floor to 0.6000. We believe that this wage floor increase would be responsive to comments from interested parties, safeguard access to care in areas at the lowest end of the current wage index distribution, and be supported by data and analyses that support a higher wage index floor, as discussed in the following subsections.

(i) Analysis of Puerto Rico Cost Reports for the CY 2019 ESRD PPS Rulemaking

For the CY 2019 ESRD PPS proposed rule (83 FR 34329 through 34330), we performed an analysis using ESRD facility cost reports and wage information specific to Puerto Rico from the BLS (*https://www.bls.gov/oes/2015/may/oes_pr.htm*). The analysis utilized data from cost reports for freestanding facilities and for hospital-based facilities in Puerto Rico for CYs 2013 through 2015.

Using these data, we calculated alternative wage indexes for Puerto Rico that combined labor quantities, that is FTEs, from cost reports with BLS wage

[4] A Laspeyres index is an index formula used in price statistics for measuring price development of the basket of goods and services consumed in the base period (*https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Glossary:Laspeyres_price_index#:~:text=The%20Laspeyres%20price%20index%20is,cost%20in%20the%20current%20period.*)

information to create two regular Laspeyres price indexes. In the context of this analysis, a Laspeyres price index can be viewed as a relative, weighted average wage of labor in each geographical area. This average combines the wages of various labor categories according to certain weights. The two indexes we considered used the same BLS-derived wages but different weights. The first index used quantity weights derived from the overall U.S. use of labor inputs. The second index used quantity weights derived from the Puerto Rico use of labor inputs. The alternative wage indexes derived from the analysis indicated that Puerto Rico's wage index likely lies between 0.5100 and 0.5500. As noted earlier in this section of this proposed rule and discussed in the CY 2019 ESRD PPS final rule (83 FR 56967), commenters have noted that both of these values are above the current wage index floor and suggest that the current 0.5000 wage index floor may be too low. Commenters pointed out CMS's analysis shows that Puerto Rico's wage index likely lies between 0.51 and 0.55, while additional analyses note that any wage index values less than 0.5936 are considered outlier values, with 0.5936 therefore as the lower wage index boundary. They expressed concern that in the CY 2019 ESRD PPS proposed rule CMS proposed a new floor of only 0.5000 even though the present methodology applied to Puerto Rico has created the only outlier in the U.S. As we stated in the CY 2019 ESRD PPS final rule (83 FR 56967), at that time, we believed that a wage index floor of 0.5000 struck an appropriate balance between providing additional payments to areas that fall below the wage floor while minimizing the impact on the ESRD PPS base rate. At the time, we conducted analyses to gauge the appropriateness of the then-current wage index floor of 0.4000 and determine whether it was too low. We did not propose to use these analyses to determine the exact value for a new wage index floor.

Specifically, as we explained in the CY 2019 ESRD PPS final rule, CMS performed a statistical outlier analysis to identify the upper and lower boundaries of the distribution of the current wage index values and remove outlier values at the edges of the distribution. In the general sense, an outlier is an observation that lies outside a defined range from other values in a population. In this case, the population of values is the various wage indexes within the CY 2019 wage index. The lower and upper quartiles (the 25th and 75th percentiles) are also used. The lower quartile is Q1 and the upper quartile is Q3. The difference (Q3 − Q1) is called the interquartile range (IQR). The IQR is used in calculating the inner and outer fences of a data set. The inner fences are needed for identifying mild outlier values in the edges of the distribution of a data set. Any values in the data set that are outside of the inner fences are identified as an outlier. The standard multiplying value for identifying the inner fences is 1.5. First, we identified the Q1 and Q3 quartiles of the CY 2018 wage index, which are as follows: Q1 = 0.8303 and Q3 = 0.9881. Next, we identified the IQR: IQR = 0.9881 − 0.8303 = 0.1578. Finally, we identified the inner fence values as shown below. Lower inner fence: Q1 − 1.5*IQR = 0.8303 − (1.5 × 0.1578) = 0.5936. This statistical outlier analysis demonstrated that any wage index values less than 0.5936 are considered outlier values, and 0.5936 as the lower boundary also suggested that the current wage index floor could be appropriately reset at a higher level.

Based on these analyses, we finalized a wage index floor of 0.5000 in the CY 2019 ESRD PPS final rule. We continued to apply the wage index floor of 0.5000 per year through CY 2022. Although we did not propose specific policies relating to the wage index floor in the CY 2022 ESRD PPS proposed rule, commenters on that rule noted that past hurricanes and the COVID–19 PHE have created infrastructure challenges that lead to high costs of dialysis care. These commenters requested CMS increase the wage index floor. In response to comments and our continued concern regarding access, in this proposed rule, we are revisiting the CY 2019 analysis, and believe that the statistical analysis of the CY 2019 data indicated that a wage index floor as high as 0.5936 would be appropriate.

(ii) Analysis of the CY 2023 ESRD PPS Proposed Rule Analytic File

We performed an analysis to compare the impact of three options to adjust the wage index floor upward using the CY 2023 ESRD PPS proposed rule analytic file. The analytic file includes qualifying data for beneficiaries for whom a 72x claim for renal dialysis services was submitted in the outpatient file setting during CY 2021. We analyzed the impact of three options for adjustment for the wage index floor: (1) wage index floor of 0.5000 (that is, no change), (2) wage index floor of 0.5500, and (3) wage index floor of 0.6000. Specifically, we examined how these three options would potentially impact the base rate, outlier thresholds, and average payment rates for all ESRD facilities.

Among the three options, we considered the wage index floor of 0.5000 as the baseline or starting point used for comparisons. We then compared the impact on various aspects of the ESRD PPS under the alternative options using the 0.5500 and 0.6000 wage index floor.

First, we examined the potential impact on the base rate. Under the baseline (wage index value of 0.5000), the proposed base rate for CY 2023 would be $264.14. The remaining two options (0.5500 floor and 0.6000 floor) would result in a base rate of $264.11 and $264.09, respectively. These options would decrease the proposed ESRD PPS base rate due to the application of the budget neutrality factor for each option, however as discussed in the following paragraph, the overall impact to ESRD PPS payments would be negligible.

Next, we examined the potential impact to the outlier thresholds. Relative to the baseline (wage index floor value of 0.5000), all options would have little or no impact on either the outlier MAP or the FDL. Lastly, we examined the potential impact to overall ESRD facility payments. After accounting for all payment adjustments under the ESRD PPS and applying the required budget neutrality factor for each option, all options would be associated with a 3.00 percent increase in projected payments for CY 2023 due to the proposed market basket update and proposed outlier FDL and MAP amounts. We estimate that the change in overall payments attributable to increasing the wage index floor would be less than 0.01 percentage point. However, we estimate that there would be a significant increase in payments to ESRD facilities located in Puerto Rico. Under the 0.5500 wage index floor option, we estimate that payments to ESRD facilities in Puerto Rico would increase by approximately 3.8 percent relative to the 0.5000 wage index floor option. Under the 0.6000 wage index floor option, we estimate that payments to Puerto Rico facilities would increase by approximately 7.6 percent relative to the 0.5000 floor. In other words, increasing the wage index floor to 0.6000 would maximize the positive impacts for ESRD facilities located in Puerto Rico while continuing to minimize the impact to overall ESRD PPS payments.

As noted previously in this section of the proposed rule, the statistical analysis presented in the CY 2019 ESRD PPS rulemaking resulted in values for the lower and upper fences for

appropriate wage index values (lower = 0.5936, upper = 0.7514). Any values in the data set that are outside of the fences are identified as an outlier. Therefore, the analysis indicated that a wage index floor of 0.5936 would be appropriate, because any wage index values less than 0.5936 or greater than 0.7514 would be considered outlier values, and a wage index value within the fences could be appropriate. For greater simplicity and public understanding, we propose to round the lower fence of 0.5936 to the nearest 0.05, to align with the increment of change that we previously adopted in the CY 2011 ESRD PPS final rule (75 FR 49116 through 49117) for historical reductions to the ESRD PPS wage index floor. As a result, after rounding to the nearest 0.05, a wage index floor of 0.6000 would be in line with the data.

We strive for a wage index floor value that maintains the accuracy of payments under the ESRD PPS, that is, has minimal impact on the base rate, outlier thresholds, and average payment rates for all ESRD facilities. Based on our analysis of several options using the most recent analytic file for this proposed rule, a value near the lower fence of 0.5936 as described in the prior paragraph would maximize the positive impacts for ESRD facilities with wage indexes below the floor while continuing to minimize the impact to overall ESRD PPS payments.

(iii) Wage Index Floor Proposed Action

Based on our re-evaluation the CY 2019 analysis and subsequent analysis of several options using the most recent analytic file for this proposed rule, we are proposing to increase the wage index floor to 0.6000. We believe our analyses support that wage index floor value and would strike the right balance between providing increased payment to areas to areas for which labor costs are higher than the current wage index for the relevant CBSAs indicate, while maintaining the accuracy of payments under the ESRD PPS and minimizing the overall impact to all ESRD facilities. In addition, we are proposing to amend § 413.231 by adding new paragraph (d) to reflect this change and to codify the wage index floor policy. We believe this proposed increase from the current 0.5000 wage index floor value would minimize the impact to the base rate while providing increased payment to areas that need it.

Currently, only rural Puerto Rico and 8 urban CBSAs in Puerto Rico receive the wage index floor of 0.5000. The next lowest wage index is the Virgin Islands CBSA with a value of 0.6004. Under this proposal, all CBSAs in Puerto Rico would be subject to the wage index floor of 0.6000. Though the proposed wage index floor value currently would only affect areas in Puerto Rico, we note that, consistent with our established policy, the proposed wage index floor value of 6.000 that would be applicable for any area that may fall below the floor.

We solicit comment on the proposal to increase the wage index floor from 0.5000 to 0.6000.

c. Proposed CY 2023 Update to the Outlier Policy

(1) Background

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of ESAs necessary for anemia management. Some examples of the patient conditions that may be reflective of higher facility costs when furnishing dialysis care would be frailty and obesity. A patient's specific medical condition, such as secondary hyperparathyroidism, may result in higher per treatment costs. The ESRD PPS recognizes high cost patients, and we have codified the outlier policy and our methodology for calculating outlier payments at § 413.237.

Section 413.237(a)(1) enumerates the following items and services that are eligible for outlier payments as ESRD outlier services. (i) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (ii) Renal dialysis laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (iii) Renal dialysis medical/surgical supplies, including syringes, used to administer renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (iv) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including renal dialysis oral-only drugs effective January 1, 2025; and (v) renal dialysis equipment and supplies, except for capital-related assets that are home dialysis machines (as defined in § 413.236(a)(2)), that receive the transitional add-on payment adjustment as specified in § 413.236 after the payment period has ended.[5]

In the CY 2011 ESRD PPS final rule (75 FR 49142), CMS stated that for purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the facility to identify the actual ESRD outlier services furnished to the patient by line item (that is, date of service) on the monthly claim. Renal dialysis drugs, laboratory tests, and medical/surgical supplies that are recognized as ESRD outlier services were specified in Transmittal 2134, dated January 14, 2011.[6] We use administrative issuances and guidance to continually update the renal dialysis service items available for outlier payment via our quarterly update CMS Change Requests, when applicable. For example, we use these issuances to identify renal dialysis oral drugs that were or would have been covered under Part D prior to 2011 in order to provide unit prices for determining the imputed MAP amounts. In addition, we use these issuances to update the list of ESRD outlier services by adding or removing items and services that we determined, based our monitoring efforts, are either incorrectly included or missing from the list.

Under § 413.237, an ESRD facility is eligible for an outlier payment if its imputed (that is, calculated) MAP amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average estimated expenditure per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted MAP amount per treatment plus the FDL amount. As described in the following paragraphs, the facility's predicted MAP amount is the national adjusted average ESRD outlier services MAP amount per treatment, further adjusted for case-mix and facility characteristics applicable to the claim. We use the term ''national adjusted average'' in this section of this proposed rule in order to more clearly distinguish the calculation of the average ESRD outlier services MAP amount per treatment from the calculation of the predicted MAP amount for a claim. The average ESRD outlier services MAP amount per treatment is based on

[5] Under § 413.237(a)(1)(vi), as of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry panel are excluded from the definition of outlier services.

[6] Transmittal 2033 issued August 20, 2010, was rescinded and replaced by Transmittal 2094, dated November 17, 2010. Transmittal 2094 identified additional drugs and laboratory tests that may also be eligible for ESRD outlier payment. Transmittal 2094 was rescinded and replaced by Transmittal 2134, dated January 14, 2011, which included one technical correction. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2134CP.pdf.*

utilization from all ESRD facilities, whereas the calculation of the predicted MAP amount for a claim is based on the individual ESRD facility and patient characteristics of the monthly claim. In accordance with § 413.237(c), ESRD facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule and codified in § 413.220(b)(4), using 2007 data, we established the outlier percentage, which is used to reduce the per treatment base rate to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments, at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the FDL amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and FDL amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140). As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the predicted outlier services MAP amounts for a patient are determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis used to compute the payment adjustments. We discuss the details of our current methodology for calculating the MAP and FDL amounts in the following section.

(2) Overview of Current Outlier Methodology

We update the national adjusted average MAP amounts and FDL amounts each year using the latest available data in the annual regulatory updates to the ESRD PPS, in accordance with our longstanding policy (75 FR 49174). As noted earlier in this section of the proposed rule, based on our longstanding policy finalized in the CY 2011 ESRD PPS final rule (75 FR 49139 through 49140), the national adjusted average MAP amounts represent the national average estimated expenditure per treatment for ESRD outlier services, adjusted by a standardization factor. As detailed in the following paragraph, when evaluating outlier eligibility for a particular patient treated in a particular facility for a particular month, this national adjusted average is further adjusted to reflect the patient-specific case-mix severity and facility characteristics. We refer to this further adjusted MAP amount as the predicted MAP amount. Unlike the national average outlier MAP amount per treatment, the predicted MAP amount varies across patients (and even across patient-months). The national adjusted average MAP amounts and FDL amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140).

Under the methodology finalized in the CY 2011 ESRD PPS final rule (75 FR 49174), each year, using the latest available ESRD PPS data, we compute the national average MAP amount, and establish the FDL amount at a level that results in projected outlier payments that equal 1.0 percent of total payments under the ESRD PPS. When setting the outlier thresholds for the ESRD PPS rule, we first identify all ESRD outlier services for all beneficiaries using the most recently complete 72x claims data, which is claims from two years prior. For example, for the CY 2022 ESRD PPS rulemaking (86 FR 61882), we used 2020 claims. For items billed using HCPCS codes, we include injectable drugs as eligible ESRD outlier services if they belong to one of the ESRD PPS functional categories but are not in one of the composite rate drug categories (both are described in Chapter 11, Section 20.3 of the Medicare Benefit Policy Manual).[7] We do not include composite rate items because they are not eligible for outlier payments, in accordance with our longstanding ESRD PPS policy of including only formerly separately billable items and services as eligible ESRD outlier services (75 FR 49138). For items billed using National Drug Codes (NDCs), we include all oral drugs included on the ESRD outlier services list, which includes oral calcimimetics (starting January 1, 2021), and oral vitamin D analogs. We also include laboratory services that are on the list of eligible ESRD outlier services published by CMS.[8] Two supply HCPCS codes are eligible for outlier payments (A4657 syringe and A4913 miscellaneous supplies).

(a) Methodology for Calculating Imputed MAP Amounts and Predicted MAP Amounts

As we explained in the CY 2011 ESRD PPS final rule (75 FR 49142), the ESRD facility must identify all ESRD outlier services furnished to the patient by line item on the monthly claim that it submits to Medicare in order to receive the outlier payment adjustment. We estimate the imputed MAP amount for these services by applying the established pricing methodologies described in the following paragraph of this proposed rule. The imputed MAP amounts for each of these services are summed and divided by the corresponding number of treatments identified on the claim to yield the imputed ESRD outlier services MAP amount per treatment.

We multiply the utilization (that is, units of ESRD outlier services reported on the 72X claim) with prices to obtain the outlier-eligible amount. We obtain the utilization only from claim lines that are fully covered by Medicare (that is, claim lines that do not include any non-covered charge amount) containing ESRD outlier services. Separately billable services that are performed in the ESRD facility during dialysis that are not related to the treatment of ESRD are not included in the outlier-eligible amount. In the CY 2011 ESRD PPS final rule (75 FR 49142), we finalized the basis for estimating imputed MAP amounts as follows. For pricing of ESRD outlier services that are Part B renal dialysis drugs reported with HCPCS codes, we use the latest Average Sales Price (ASP) data, which is updated quarterly. ESRD outlier services that are renal dialysis drugs formerly covered under Part D and reported with NDCs are priced based on the national average pricing data retrieved from the Medicare Prescription Drug Plan Finder, which reflect pharmacy dispensing and administration fees. For ESRD outlier services that are laboratory tests billed using HCPCS codes, we use the latest payment rates from the Clinical Laboratory Fee Schedule. For renal dialysis supplies used to administer ESRD outlier services Part B drugs (for example, syringes), we estimate MAP amounts based on the predetermined fees that apply to these items, that is, we pay $0.50 for each syringe identified on an ESRD facility's claims form. For other medical/surgical supplies such as intravenous sets and gloves, the Medicare Claims Processing Manual currently allows Medicare contractors to elect among various options to price these supplies, such as the Drug Topics Red Book, Med-Span, or First Data Bank

[7] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf.*

[8] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Outlier_Services.*

(CMS Pub. 100–04, Chapter 8, § 60.2.1). We sum up the outlier-eligible amounts for drugs, laboratory tests, and supplies separately.

Next, we inflate the outlier-eligible amounts calculated for drugs, laboratory tests, and supplies from the latest available prices to forecasted prices for the rule year.[9] For example, in the CY 2022 ESRD PPS rulemaking (86 FR 61882), we used 2021 prices inflated to the forecasted prices for CY 2022. Then, we add the inflated drug, laboratory test, and supply amounts and multiply the total amount by 0.98, in accordance with the budget neutrality requirement under section 153(b) of MIPPA. Lastly, we divide the amount by the number of treatments reported on the claim in order to obtain imputed MAP amount per treatment.

After calculating the imputed MAP amount per treatment, we then compute the predicted MAP amount for the claim. As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the patient-specific predicted MAP amount is equal to the national adjusted average MAP amount multiplied by the patient-specific case-mix adjusters. The national average MAP amount is adjusted by applying a standardization factor that reflects the national average of patients' outlier services case-mix severity. We apply this standardization factor in order to avoid systematically biasing the national average MAP amount calculation, which would result in setting the FDL amounts at a level that is too low. By applying the standardization factor to the national average MAP amount when calculating the patient-specific predicted MAP amount, we ensure that total imputed MAP dollars equal total predicted MAP dollars. The methodology for calculating this standardization factor is discussed in detail in the following section.

(b) Methodology for Calculating Case-Mix Standardization Factor and National Adjusted Average MAP Amount

We publish the national adjusted average MAP amount each year in the ESRD PPS proposed and final rule along with the adjustment factor. We currently use the ESRD outlier services multipliers that are the separately billable (SB) multipliers developed from the regression analysis used in the CY 2016 ESRD PPS refinement (80 FR 68993 and 80 FR 69002). As discussed in the CY 2016 ESRD PPS final rule (80 FR 68970), in accordance with section 632(c) of ATRA, we analyzed the case-mix payment adjustments under the ESRD PPS using more recent data. We revised the adjustments by changing the adjustment payment amounts based on our updated regression analysis using CYs 2012 and 2013 ESRD claims and cost report data. There was no change in the ESRD PPS outlier methodology for CY 2016, however, we updated the ESRD outlier services multipliers (80 FR 69008). The current ESRD outlier services multipliers are presented in Tables 10 and 11 in this section. A more detailed description of the steps is provided in the following paragraphs.

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TABLE 10: Adult Outlier Services Multipliers

Variable	Outlier Services Multipliers
Age	
18-44	1.044
45-59	1.000
60-69	1.005
70-79	1.000
80+	0.961
Body surface area (BSA) (per 0.1 m^2)	1.000
Underweight (BMI < 18.5)	1.090
Time since onset of renal dialysis < 4 months	1.409
Facility low volume status	0.955
Comorbidities	
Pericarditis (acute)	1.209
Gastro-intestinal tract bleeding (acute)	1.426
Bacterial pneumonia (acute)	---
Hereditary hemolytic or sickle cell anemia (chronic)	1.999
Myelodysplastic syndrome (chronic)	1.494
Monoclonal gammopathy (chronic)	---
Rural	0.978

[9] We use a blended 4-quarter moving average of the ESRDB market basket price proxies for pharmaceuticals to inflate drug prices to the rule year. We inflate laboratory test prices to the rule year based on the estimated change in payment rates under the Clinical Laboratory Fee Schedule, using a CPI forecast to estimate changes for years in which a new survey will be implemented. For supplies, we apply a 0 percent inflation factor, because these prices are based on predetermined fees or prices established by the Medicare contractor.

TABLE 11: Pediatric Outlier Services Multipliers

Patient Characteristics		Outlier Services Multipliers		
Age	Modality	Population%	Separately Billable Multiplier	Expanded Bundle Payment Multiplier
<13	PD	27.62%	0.410	1.063
<13	HD	19.23%	1.406	1.306
13-17	PD	20.19%	0.569	1.102
13-17	HD	32.96%	1.494	1.327

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As discussed in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49140), in order to calculate the predicted MAP amount per treatment, we first compute the weighted mean of the imputed MAP amounts per treatment, separately for adult and pediatric patients, at the national level. Then, for each claim, we identify the patient's case-mix adjustments that are applicable for the month based on conditions recorded on the 72x claims, and multiply all applicable ESRD outlier services multipliers together to obtain the combined ESRD outlier services multiplier. For pediatric patients, the ESRD outlier services multipliers are the age and modality adjusters; for adults, the ESRD outlier services multipliers include all case-mix and facility-level adjusters. We then calculate the national per-treatment weighted mean of the combined outlier services multipliers for adult and pediatric patients separately. We calculate one standardization factor for adult patients and one for pediatric patients. Each standardization factor is calculated as follows:

1/(weighted mean of the combined outlier services multipliers).

We calculate the adjusted national average outlier MAP amount per treatment by multiplying the per-treatment weighted mean of the imputed outlier MAP amount per treatment by the standardization factor, separately for adults and pediatric patients.

In order to calculate the predicted outlier MAP amount per treatment for each claim, we multiply the national adjusted average MAP amount per treatment, separate for adults and pediatrics, by all applicable outlier services multipliers for that claim.

(c) Methodology for Calculating FDL Amounts

In accordance with our longstanding methodology, FDL amounts are calculated separately for adult and pediatric patients so that projected outlier payments equal 1.0 percent of total ESRD PPS payments (75 FR 49142 through 49144). For the FDL amounts, we begin by computing total payments for the particular rule year separately for adults and pediatric patients. We include all anticipated updates such as the wage index, market basket update, and productivity adjustment. For each claim, we compute:

Outlier payment per Treatment = Outlier loss share amount * (Imputed MAP amount per Treatment − (Threshold per Treatment)) =
0.8 * (Imputed MAP amount per Treatment − (Predicted MAP amount per Treatment + FDL))

A claim is eligible for an outlier payment if the imputed MAP amount per treatment − (Threshold per Treatment) >0.

We simulate total outlier payments, separately for adult and pediatric patients, starting with the prior rule year's FDL amounts. If the sum of projected outlier payments for the particular rule year is higher than 1.0 percent of total payments, we increase the FDL amounts in order to decrease the amount of outlier payments. In contrast, if projected outlier payments are lower than 1.0 percent of total payments, we decrease the FDL amounts in order to increase the amount of outlier payments. We determine the separate adult and pediatric FDL amounts that bring projected adult and pediatric outlier payments to 1.0 percent of total payments for each patient population. We announce the proposed and final MAP amounts and FDL amounts in the annual ESRD PPS proposed and final rules, respectively.

(d) Example of Outlier Calculation

The following is an example of the calculation of the outlier payment. John, a 68-year-old male Medicare beneficiary, is 187.96 cm. in height and weighs 95 kg. John receives hemodialysis 3 times weekly. In January 2022, he was hospitalized for 4 days for a compound ankle fracture. During the hospitalization John did not undergo any dialysis treatments. After discharge John resumed his dialysis treatments, but required additional laboratory testing and above-average doses of several injectable drugs, particularly EPO, to return his hemoglobin levels to the normal range. During January 2022, John received 9 hemodialysis treatments at his usual ESRD facility. The facility submitted a claim for eligible ESRD outlier services including drugs and biological products, laboratory tests, and supplies totaling $3,000.00.

We begin by computing the predicted MAP amount per treatment based on the ESRD outlier services case-mix adjustment factors applicable to John. These factors are age and BSA. John's BSA is 2.2161. Applying the ESRD outlier services multiplier set forth in Table 10 of this proposed rule for BSA, John's ESRD outlier services payment multiplier (PM) for BSA is computed as follows:

$1.000^{(2.2161-1.9)/0.1} = 1.000^{3.16135} = 1.000$

Using this calculated PM for BSA and the PM for age from Table 10, John's outlier services PM is calculated as:

1.005 * 1.000 = 1.005

For CY 2022, the national average MAP amount per treatment for adult patients is $42.75. Therefore, the predicted MAP amount per treatment for John is: $42.75 * 1.005 = $42.96.

Next, we determine the imputed MAP amount per treatment which reflects the estimated expenditure for ESRD outlier services incurred by the ESRD facility. John's imputed MAP amount per treatment is equal to the total amount of

drugs and biological products, laboratory tests, and supplies submitted on the claim, divided by the number of treatments. We calculate this as: $3000.00/9 = $333.33.

Next, we must determine if John's ESRD facility is entitled to outlier payments for John's January claim by comparing the predicted MAP amount to the threshold per treatment. We calculate the threshold per treatment by adding the CY 2022 FDL amount to the predicted MAP amount for John.

The threshold amount for John is calculated to reflect the case-mix adjustments for age and BSA.

Threshold = Predicted MAP amount ($42.96) + FDL ($75.39) = $118.35

Because John's imputed MAP amount per treatment was $333.33, which exceeds the sum of the predicted MAP amount and FDL amount ($118.35), John's ESRD facility is eligible for outlier payments.

The outlier payments for John's 9 treatments are calculated as the amount by which the imputed MAP amount exceeds the threshold, then multiplied by the 80 percent loss-sharing ratio.

Imputed MAP amount minus Threshold: $333.33 − $118.35 = $214.98

Outlier payments per treatment: $214.98 * .80 = $171.98

Total outlier payments: $171.98 * 9 = $1,547.82

(3) Current Issue and Concerns From Interested Parties

For several years, outlier payments have consistently landed below the target of 1.0 percent of total ESRD PPS payments. Commenters have raised concerns that the methodology we currently use to calculate the outlier payment adjustment results in underpayment to ESRD facilities, as money was removed from the base rate to balance the outlier payment (85 FR 71409, 71438 through 71439; 84 FR 60705 through 60706; 83 FR 56969). Therefore, they have urged us to adopt an alternative modeling approach that accounts for declining trends in spending for eligible ESRD outlier services over time.

MedPAC echoed these concerns in a comment in response to the CY 2021 ESRD PPS proposed rule (85 71438 through 71440), and also suggested that the introduction of calcimimetics as an eligible ESRD outlier service could perpetuate this issue. MedPAC predicted that if calcimimetic use decreases between 2019 (when the products were paid under the ESRD PPS using the TDAPA) and 2021 (when the products would be paid as part of the ESRD PPS base rate), the outlier threshold would be set too high, and outlier payments would be lower than the target of 1.0 percent of total CY 2021 payments.

In response to the concerns raised by MedPAC and others, CMS has been conducting research in conjunction with its contractor, including holding three technical expert panels (TEPs), to investigate possible improvements to the ESRD PPS payment methodologies. As discussed in the CY 2022 ESRD PPS proposed rule (86 FR 36401 through 36402), during the second and third TEP meetings convened by the CMS contractor in 2019 and 2020, panelists discussed their specific concerns regarding the current outlier policy and alternative methodologies to achieve the 1.0 percent outlier target. Some TEP panelists and interested parties have strongly advocated that we establish a new outlier methodology using alternative modeling approaches that account for trends in formerly separately billable spending over time. Other interested parties advocated for changing the outlier percentage. Overall, panelists expressed support for any change to outlier calculations that result in total outlier payments being closer to the target.

In the CY 2022 ESRD PPS proposed rule (86 FR 36402), we stated that we were considering potential revisions to the calculation of the outlier threshold to address concerns from interested parties. In that rule, we presented the information that was previously provided to the TEP in order to solicit comments from interested parties in the dialysis community and the public (86 FR 36402). We published an RFI to solicit comments on the approaches noted in the previous paragraph and any information that would better inform future modifications to the methodology (86 FR 36402). In addition to generally seeking input regarding calculating the outlier payment adjustment, we specifically requested responses to the following questions:

- An alternative approach could be to estimate the retrospective FDL trend by using historical utilization data. How many years of data should be included in calculation of this trend to best capture changes in treatment patterns?
- The simulation of the FDL can be improved by better anticipating changes in utilization of ESRD outlier services. What are the factors that affect the use of ESRD outlier services over time, and to what extent should CMS try to forecast the effect of these factors?
- As ESRD beneficiaries can now choose to enroll in Medicare Advantage (MA), please describe any anticipated effects of this enrollment change on the use of ESRD outlier services in the ESRD PPS.
- Adoption of the suggested methodology may account for systematic changes in the use of high cost outlier items. However, inherently unpredictable changes may still push the outlier payment off the 1.0 percent target. Please comment on the acceptability of the following payment adjustment methods: Payment reconciliation in the form of an add-on payment adjustment or a payment reduction might be necessary to bring payments in line with the 1 percent target. An add-on payment adjustment would be distributed after sufficient data reveal the magnitude of the deviation (1 year after the end of the payment year). The distribution of these monies could be done via a lump sum or via a per-treatment payment add-on effective for 1 year. This add-on payment adjustment would be paid irrespective of the outlier claim status in that year. A payment reduction could take the form of a reduction in the base rate, also to be applied 1 year after the end of the payment year.

As discussed in the CY 2022 ESRD PPS final rule (86 FR 61996), we received numerous public comments in response to our RFI on payment reform under the ESRD PPS. As discussed in a more detailed comment summary on the CMS website,[10] we received comments from major national patient and provider organizations and MedPAC on the RFI regarding the outlier policy. Commenters reiterated their concerns that outlier payments under the ESRD PPS have not achieved the 1.0 percent target since the system was implemented. Commenters focused on three main suggestions for the outlier policy: (1) reducing the target outlier percentage to 0.5 or 0.6 percent, which commenters argued would more closely align with the historical percentage that has been paid under the ESRD PPS; (2) changing the methodology used to calculate the FDL and MAP amounts in order to better account for not only historical trends in utilization but also changes in prices and utilization of new and innovative products; and (3) re-allocating money from the ESRD PPS that is not paid out for outliers—either by allowing unspent funds to apply to a subsequent year's withhold amount or establishing a payment mechanism to support ESRD facilities' activities aimed at reducing health disparities.

[10] *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/ESRDpayment/Educational_Resources.*

(4) Proposed Changes to the Outlier Methodology for CY 2023

In response to significant public comments received over many years, we are proposing changes to the outlier policy for CY 2023 and subsequent years. In developing these proposed changes, we considered the three main suggestions that commenters raised in response to the CY 2022 RFI.

First, we considered the recommendation from commenters that CMS reduce the outlier percentage from 1.0 percent to 0.5 percent or 0.6 percent. Although this approach would allow us to potentially increase payment under the ESRD PPS base rate for treatment of those patients who do not qualify for outlier payments, we are chiefly concerned that this approach would not directly address the root cause of outlier payments totaling less than 1 percent of overall ESRD PPS payments in prior years. Although reducing the target outlier percentage would reduce the size of outlier payments relative to total ESRD PPS payments, we are concerned that if we do not change the methodology that we use to prospectively determine the outlier threshold, we may continue to not meet even the lower target outlier percentage.

Additionally, as discussed in the CY 2011 ESRD PPS final rule (75 FR 49134), we established the 1.0 percent outlier percentage because it struck an appropriate balance between our objective of paying an adequate amount for the most costly, resource-intensive patients while providing an appropriate level of payment for those patients who do not qualify for outlier payments. We are concerned that a reduced outlier percentage may not provide the appropriate level of payment for outlier cases, and may not protect access for beneficiaries whose care is unusually costly. This is because if we were to decrease the target outlier percentage, we would need to significantly increase the FDL amounts, which would make it more difficult for ESRD facilities to receive outlier payment based on their claims. Therefore, after careful consideration, we are not proposing to reduce the outlier percentage.

Next, we considered the recommendation to re-allocate money from the ESRD PPS that is not paid out for outliers. As explained earlier in this section of the proposed rule, we solicited comments in the CY 2022 ESRD PPS proposed rule (86 FR 36402) about a potential payment reconciliation in the form of an add-on payment adjustment or a payment reduction, which might be necessary to bring outlier payments in line with the 1.0 percent target. As we described in the detailed RFI comment summary document on the CMS website,[11] several commenters supported this idea, and recommended that CMS allow unspent outlier funds from the prior year to reduce the amount set aside for outliers in the next year. Other commenters suggested that unspent outlier funds could be used to fund initiatives that support health equity. One national dialysis organization pointed out that lags in the claims process and refiling of claims, often over different calendar years, would present challenges to such an approach. This organization noted that these challenges could make it difficult to accurately calculate the amount of the add-on payment adjustment or ''clawback'' payment amount for each year. We agree with the concerns this organization raised, and believe that these challenges would make it difficult to accurately operationalize commenters' recommendations that we allow unspent funds to apply to a subsequent year's withhold amount or establish a payment mechanism to support ESRD facilities' activities aimed at reducing health disparities. Therefore, after careful consideration, we are not proposing to establish a payment reconciliation methodology for the ESRD PPS outlier policy.

Lastly, we considered the feedback from interested parties and commenters in the past ESRD PPS TEPs and in comments to the RFI in the CY 2022 ESRD PPS proposed rule regarding the methodology used to calculate the FDL amounts. As commenters have previously noted, the current methodology that we use to prospectively calculate the FDL amounts has not been able to effectively account for declining use of eligible ESRD outlier services (that is, separately billable items and services prior to 2011) each year since the implementation of the ESRD PPS. For example, the CY 2021 FDL amounts ($48.33 for adult and $41.04 pediatric patients) were added to the predicted MAP amounts to determine the outlier thresholds using 2019 data. The outlier MAP amount continued to fall from 2019 to 2021. Consequently, in 2021 claims, outlier payments comprised approximately 0.4 percent of total ESRD PPS payments, demonstrating that the use of 2019 data resulted in thresholds too high to achieve the targeted 1.0 percent outlier payment.

Several organizations that commented in response to the RFI[12] in the CY 2022 ESRD PPS proposed rule expressed that using a retrospective FDL trend based on historical utilization data would provide a better calculation of the appropriate prospective FDL amounts. These organizations also cautioned that such a methodology would remain sensitive to changes in utilization or price increases for new and innovative products. Commenters suggested that such a methodology would likely not succeed in estimating the appropriate FDL amounts in years when there are significant changes to the ESRD PPS, such as in years that immediately follow the end of a period during which CMS has paid for a product using the TDAPA or TPNIES payment adjustments under the ESRD PPS. MedPAC suggested that CMS consider modeling alternative approaches to establishing the outlier threshold and use an approach that reflects the trend over time in spending for items in the ESRD PPS bundled payment that were separately billable prior to 2011.

In the CY 2022 ESRD PPS proposed rule (86 FR 36402), we also solicited comments on any anticipated effects enrollment changes in MA plans might have on the use of ESRD outlier services. National provider organizations pointed out that to the extent that MA plans are not permitted to systematically include healthier ESRD beneficiaries and exclude costly beneficiaries, there would seem to be little impact on the outlier pool. They expressed concern about the decision[13] to eliminate network adequacy standards that apply to ESRD facilities.

[11] *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/ESRDpayment/Educational_Resources.*

[12] *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/ESRDpayment/Educational_Resources.*

[13] We believe the commenters were referring to a CMS decision to remove outpatient dialysis from the list of facility types subject to network adequacy standards and require that MA organizations submit an attestation that it has as an adequate network that provides the required access and availability to dialysis services, including outpatient facilities. CMS indicated in the Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program (CMS–4190–F) final rule that we believe there is more than one way to access medically necessary dialysis care and that we wanted plans to exercise all of their options to best meet a beneficiary's health care needs. (85 FR 33796, 33852 through 33866). Further, regardless of whether a facility or provider specialty type is subject to network adequacy standards, MA organizations are required in § 422.112(a)(3) to arrange for health care services outside of the plan provider network when network providers are unavailable or inadequate to meet an enrollee's medical needs. Section 422.112(a)(10) requires MA plans to ensure access and availability to covered services consistent with the prevailing community pattern of health care delivery in the areas served by the network. (85 FR 33858 through 33860).

They predicted these decisions would discourage many ESRD patients from enrolling in MA plans, especially those needing specialized treatment or requiring additional medications. To the extent this scenario were to occur, commenters argued that it could result in ''outlier'' patients, specifically, those sicker, costlier patients, remaining in traditional Medicare and the healthier, less costly patients enrolling in MA plans.

Based on these comments, we are proposing an approach that would account for the historical trend in spending for formerly separately billable items and services and would also effectively account for the introduction of new and innovative products under the ESRD PPS. We believe that our proposed methodology would also adapt to changes in the ESRD PPS patient population, such as the potential scenario that commenters raised in which costlier ''outlier'' patients might remain in traditional Medicare while healthier, less costly patients enroll in MA plans.

As we discussed earlier in this section of the proposed rule, our current methodology prospectively calculates the adult and pediatric FDL and MAP amounts based on simulated outlier payments. The utilization of outlier services for these simulated outlier payments comes from a single year of ESRD PPS claims, and the prices come from the pricing methodology described earlier in this section of the proposed rule using latest available prices inflated to forecasted prices for the rule year. Under the current methodology, we prospectively set the adult and pediatric FDL amounts so that simulated outlier payments for the rule year are estimated to equal 1.0 percent.

For CY 2023 and subsequent years, we are proposing to continue to calculate the adult and pediatric MAP amounts for the rule year (CY 2023) following our established methodology, but we are proposing to prospectively calculate the adult FDL amounts based on the historical trend in FDL amounts that would have achieved the 1.0 percent outlier target in the 3 most recent available data years. We are also proposing to adjust the calculation of the historical FDL trend for years that immediately follow the end of a period during which CMS has paid for a product using the TDAPA or TPNIES payment adjustments under the ESRD PPS. We note that we are not proposing to apply this method to pediatric FDL amount calculations, as the pediatric population is too small to reliably use this method.

We are proposing the following steps for prospectively calculating the adult FDL amounts:

- *Step 1:* Use ESRD PPS claims from the 3 most recent available data years, relative to the rule year. For CY 2023, this would include data from CY 2019, CY 2020, and CY 2021. Using these claims, the projected base rate for the rule year, and the latest available prices of ESRD outlier services, we would use our established methodology to calculate the FDL amounts that would have achieved the 1.0 percent outlier target for each year. In the following steps, we refer to these calculated FDL amounts as the ''retrospective'' FDL amounts.
- *Step 2:* If any items or services that were previously paid for using the TDAPA or TPNIES in any of the 3 most recent available data years would be ESRD outlier services for the rule year, then we would also calculate an alternative series of retrospective FDL amounts. This alternative series would account for any new ESRD outlier services, that is, any ESRD outlier services for the rule year that were previously paid for using the TDAPA or TPNIES in any of the 3 most recent available data years. In the following steps, we refer to this alternative series of retrospective FDL amounts as the ''adjusted'' retrospective FDLs. Specifically, we would calculate the adjusted retrospective FDL amounts as follows:

++ If a new ESRD outlier service was paid for using the TDAPA or TPNIES in the most recent available data year, as in the case of calcimimetics in the CY 2020 data used for the CY 2022 ESRD PPS rulemaking, then we would calculate the first retrospective FDL amount for that year using the latest available prices and historical utilization of ESRD outlier services that includes TDAPA or TPNIES utilization for the new ESRD outlier service. We would also calculate a second retrospective FDL amount for that year that excludes the new ESRD outlier service. In order to calculate the adjusted retrospective FDLs for the preceding 2 data years, we would take the difference between the corresponding FDL amount with and without the new ESRD outlier service for the most recent data year, and add this amount to each retrospective FDL amount calculated in Step 1. For CY 2023, we would add the difference calculated for CY 2021 to the retrospective FDL amounts for CY 2020 and CY 2019.

++ If a new ESRD outlier service first became eligible in the most recent available data year, as in the case of calcimimetics in the CY 2021 data used for this CY 2023 ESRD PPS proposed rule, then we would calculate the first retrospective FDL amount for the most recent data year using the latest available prices and historical utilization of ESRD outlier services. We would also calculate a second retrospective FDL amount for that year that excludes the new ESRD outlier service. In order to calculate the adjusted retrospective FDL amounts for the preceding 2 data years, we would take the difference between the corresponding FDL amount with and without the new ESRD outlier service for the most recent data year, and add this amount to each retrospective FDL amount calculated in Step 1. For CY 2023, we would add the difference calculated for CY 2021 to the retrospective FDL amounts for CY 2020 and CY 2019.

++ If a new ESRD outlier service first became eligible in the second most recent available data year, as in the case of calcimimetics in the CY 2022 data that we would expect to use for the CY 2024 rulemaking, then we would calculate retrospective FDL amounts for the most recent two data years using the latest available prices and historical utilization of outlier services. For the earliest historical year, in which the new ESRD outlier service was still being paid for using the TDAPA or the TPNIES, we would also calculate a second retrospective FDL amount for that year that excludes the new ESRD outlier service. In order to calculate the adjusted retrospective FDL amount for the earliest historical year, we would take the difference between the corresponding FDL amount with and without the new ESRD outlier service in the second most recent available data year, and add this amount to the retrospective FDL amount calculated in Step 1. For CY 2023, we would add the difference calculated for CY 2020 to the retrospective FDL amount for CY 2019.

++ If a new ESRD outlier service first became outlier eligible earlier than any of the 3 most recent available data years, we would not calculate any adjusted retrospective FDL amounts for that item or service. For example, for CY 2025, we would not calculate any adjusted retrospective FDL amounts to account for calcimimetics in the CY 2021, CY 2022, and CY 2023 claims. We would calculate only the series of retrospective FDL amounts for these years in accordance with Step 1.

- *Step 3:* Using either the series of retrospective FDL amounts or adjusted retrospective FDL amounts, as appropriate, for the 3 most recent available data years, we would use a

linear regression to calculate the historical trend in FDL amounts. We would project this trend forward to determine the appropriate FDL amount for the rule year.

For illustration purposes, Figure 1 presents an example of the adult retrospective FDL amounts and adjusted retrospective FDL amounts calculated for CY 2019, CY 2020, and CY 2021, as well as the projected FDL trend through CY 2023, under our proposed methodology. The adjusted retrospective FDL amounts shown in Figure 1 would account for the difference in retrospective FDL amounts calculated with and without calcimimetics, which became ESRD outlier services beginning January 1, 2021. Figure 1 illustrates how the proposed methodology would incorporate data for new ESRD outlier services while continuing to account for the downward historical trend in spending for formerly separately billable items and services.

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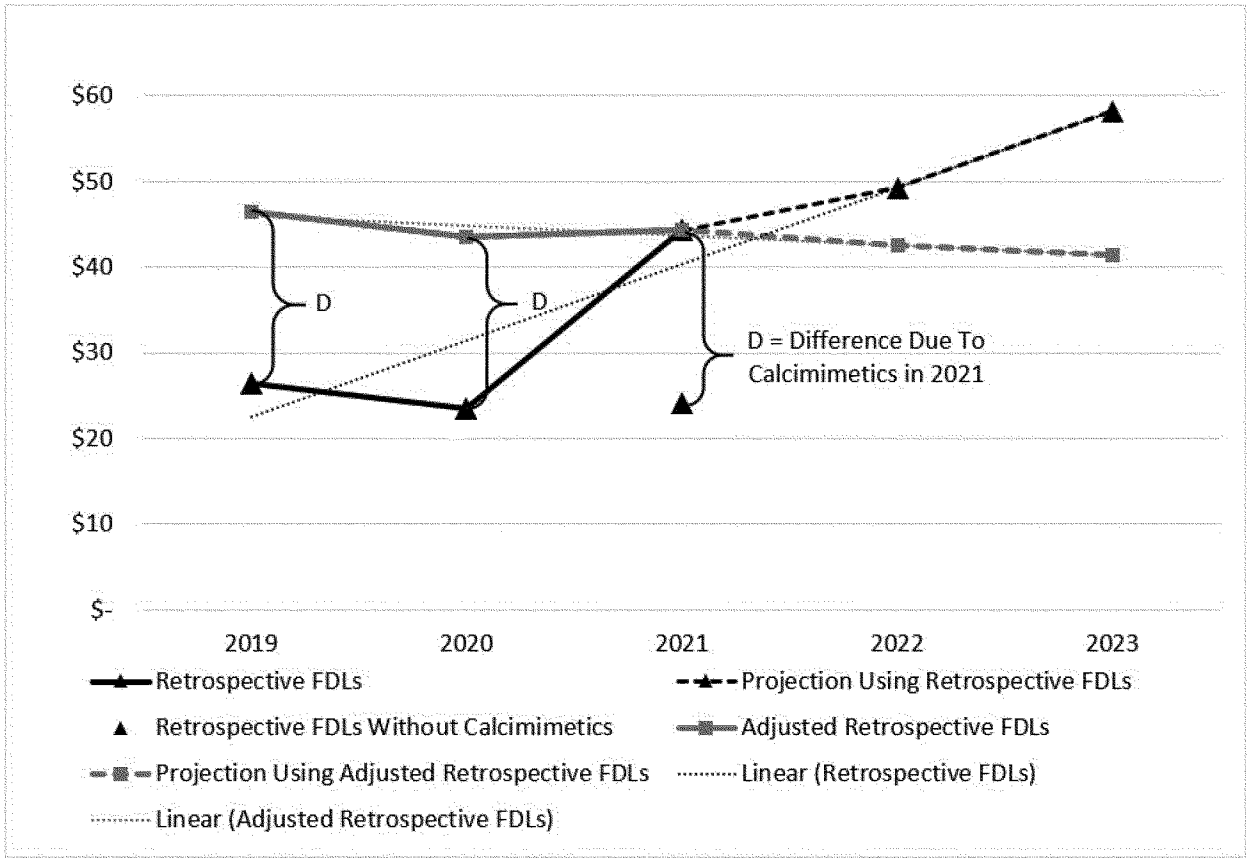
Figure 1. Proposed Retrospective FDL Amounts and Adjusted Retrospective FDL Amounts (CY 2019 through CY 2021) and Their Corresponding Projected FDLs through CY 2023 for Adults



(5) Proposed CY 2023 Update to the Outlier Services MAP Amounts and FDL Amounts

We recognize that the utilization of ESAs and other outlier services have continued to decline under the ESRD PPS, and that we have lowered the MAP amounts and FDL amounts every year under the ESRD PPS. As discussed in the CY 2022 ESRD PPS final rule (86 FR 61883), CY 2020 claims data showed outlier payments represented approximately 0.6 percent of total payments. CY 2021 claims data show outlier payments represent approximately 0.4 percent of total payments. Accordingly, as discussed in section II.B.1.c.(4) of this proposed rule, we are proposing to change our ESRD PPS outlier methodology to better target 1.0 percent of total payments. We are proposing that the outlier services MAP amounts and pediatric FDL amounts for CY 2023 would be derived from claims data from CY 2021, consistent with our policy to base any adjustments made to the MAP amounts under the ESRD PPS upon the most recent data year available. We are proposing that the adult FDL amounts for CY 2023 would be derived from the projected FDL trend calculated according to the proposed methodology described in section II.B.1.c.(4) of this proposed rule.

The impact of this proposed update is shown in Table 12, which compares the outlier services MAP amounts and FDL amounts used for the outlier policy in CY 2022 with the updated proposed estimates for this rule. The estimates for the proposed CY 2023 MAP amounts, which are included in Column II of Table 12, were inflation adjusted to reflect projected 2023 prices for ESRD outlier services.

TABLE 12: Outlier Policy: Impact of Proposal to Use Updated Data for the Outlier Policy

	Column I Final outlier policy for CY 2022 (based on 2020 data, price inflated to 2022)*		Column II Proposed outlier policy for CY 2023 (based on 2021 data, price inflated to 2023)**	
	Age < 18	Age >= 18	Age < 18	Age >= 18
Average outlier services MAP amount per treatment	$ 25.91	$ 44.49	$24.19	$38.42
Adjustments				
Standardization for outlier services	1.0693	0.9805	1.0809	0.9785
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$27.15	$42.75	$25.62	$36.85
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$26.02	$75.39	$21.51	$40.75
Patient-month-facilities qualifying for outlier payment	12.89%	7.08%	13.58%	11.54%

*Column I was obtained from Column II of Table 1 from the CY 2022 ESRD PPS final rule (86 FR 61883).
**The proposed FDL amount for adults incorporates retrospective adult FDL amounts calculated using data from CYs 2019, 2020, and 2021.

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As demonstrated in Table 12, the estimated FDL per treatment that determines the CY 2023 outlier threshold amount for adults (Column II; $40.75) is lower than that used for the CY 2022 outlier policy (Column I; $75.39). The lower threshold is accompanied by a decrease in the adjusted average MAP for outlier services from $42.75 to $36.85. For pediatric patients, there is a decrease in the FDL from $26.02 to $21.51. There is a corresponding decrease in the adjusted average MAP for outlier services among pediatric patients, from $27.15 to $25.62.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2023 will be 11.54 percent for adult patients and 13.58 percent for pediatric patients, based on the 2021 claims data and proposed methodology described in section II.B.1.c.(4) of this proposed rule. The outlier MAP and FDL amounts continue to be lower for pediatric patients than adults due to the continued lower use of outlier services (primarily reflecting lower use of ESAs and other injectable drugs).

(6) Outlier Percentage

In the CY 2011 ESRD PPS final rule (75 FR 49081) and under § 413.220(b)(4), we reduced the per treatment base rate by 1 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments as described in § 413.237. Based on the 2021 claims, outlier payments represented approximately 0.4 percent of total payments, which is below the 1 percent target due to declines in the use of outlier services. Recalibration of the thresholds using 2021 data and the proposed methodology described in section II.B.1.c.(4) of this proposed rule are expected to result in aggregate outlier payments closer to the 1 percent target in CY 2022. We believe the update to the outlier MAP and FDL amounts for CY 2023 would increase payments for ESRD beneficiaries requiring higher resource utilization. This would move us closer to meeting our 1 percent outlier policy goal, because we are using more current data for computing the MAP and FDL amounts, which is more in line with current outlier services utilization rates. We also note that recalibration of the FDL amounts would result in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments.

d. Proposed Impacts to the CY 2023 ESRD PPS Base Rate

(1) ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), CMS established the methodology for calculating the ESRD PPS per-treatment base rate, that is, the ESRD PPS base rate, and calculating the per treatment payment amount, which are codified at § 413.220 and § 413.230. The CY 2011 ESRD PPS final rule also provides a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate for projected outlier payments and budget neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. Specifically, the ESRD PPS base rate was developed from CY 2007 claims (that is, the lowest per patient utilization year as required by section 1881(b)(14)(A)(ii) of the Act), updated to CY 2011, and represented the average per treatment MAP for composite rate and separately billable services. In accordance with section 1881(b)(14)(D) of the Act and our regulation at § 413.230, the per-treatment payment amount is the sum of the ESRD PPS base rate, adjusted for the patient specific case-mix adjustments,

applicable facility adjustments, geographic differences in area wage levels using an area wage index, and any applicable outlier payment, training adjustment add-on, TDAPA, and TPNIES.

(2) Annual Payment Rate Update for CY 2023

We are proposing an ESRD PPS base rate for CY 2023 of $264.09. This proposed update reflects several factors, described in more detail as follows:

Wage Index Budget-Neutrality Adjustment Factor: We compute a wage index budget-neutrality adjustment factor that is applied to the ESRD PPS base rate. For CY 2023, we are not proposing any changes to the methodology used to calculate this factor, which is described in detail in the CY 2014 ESRD PPS final rule (78 FR 72174). We computed the proposed CY 2023 wage index budget-neutrality adjustment factor using treatment counts from the 2021 claims and facility-specific CY 2022 payment rates to estimate the total dollar amount that each ESRD facility would have received in CY 2022. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2023. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the proposed CY 2023 ESRD PPS wage index and proposed labor-related share for CY 2023. As discussed in section II.B.1.b of this proposed rule, the proposed ESRD PPS wage index for CY 2023 includes an update to the most recent hospital wage data and continued use of the 2018 OMB delineations. Additionally, as discussed in section II.B.1.b(3)(b)(iii) of this proposed rule, we are proposing to increase the ESRD PPS wage index floor from 0.5000 to 0.6000 and to apply a permanent 5-percent cap on any decrease to an ESRD facility's wage index from its wage index in the prior year, regardless of the circumstances causing the decline. The total of these payments becomes the new CY 2023 amount of wage-adjusted expenditures for all ESRD facilities. The wage index budget-neutrality factor is calculated as the target amount divided by the new CY 2023 amount. When we multiplied the wage index budget neutrality factor by the applicable CY 2023 estimated payments, aggregate payments to ESRD facilities would remain budget neutral when compared to the target amount of expenditures. That is, the wage index budget neutrality adjustment factor ensures that wage index adjustments do not increase or decrease aggregate Medicare payments with respect to changes in wage index updates. The CY 2023 proposed wage index budget-neutrality adjustment factor is 0.999997. This application would yield a CY 2023 ESRD PPS proposed base rate of $257.90 prior to the application of the market basket increase factor ($257.90 × 0.999997= $257.90). This CY 2023 proposed wage index budget-neutrality adjustment factor reflects the impact of all proposed wage index changes, including the proposed CY 2023 ESRD PPS wage index and labor-related share, proposed increase to the wage index floor, and proposed permanent 5-percent cap on wage index decreases.

For purposes of illustration and analysis, we also calculated a separate budget neutrality factor in order to estimate the impact that the proposed permanent 5-percent cap on wage index decreases would have on CY 2023 ESRD PPS payments. Following the steps described earlier in this section of the proposed rule, we divided estimated payments without the proposed 5-percent cap by estimated payments with the cap. We calculated the resulting budget neutrality factor as 0.999910. Applying this budget neutrality factor to the ESRD PPS base rate, we estimate that the proposed permanent 5-percent cap would result in a $0.02 decrease to the ESRD PPS base rate ($257.90 × 0.999910 = $257.88). The overall CY 2023 proposed wage index budget-neutrality adjustment factor is higher, because the effect on budget neutrality of the proposed 5-percent cap is offset by the effect of the proposed increase to the labor-related share.

Market Basket Increase: Section 1881(b)(14)(F)(i)(I) of the Act provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by the ESRD market basket percentage increase factor. The latest CY 2023 projection of the proposed ESRDB market basket percentage increase factor is 2.8 percent. In CY 2023, this amount must be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, as required by section 1881(b)(14)(F)(i)(II) of the Act. As discussed previously in section II.B.1.a of this proposed rule, the proposed productivity adjustment for CY 2023 is 0.4 percent, thus yielding a proposed update to the base rate of 2.4 percent for CY 2023. Therefore, the proposed CY 2023 ESRD PPS base rate is $264.09 ($257.90 × 1.024 = $264.09).

e. Update to the Average per Treatment Offset Amount for Home Dialysis Machines

In the CY 2021 ESRD PPS final rule (85 FR 71427), we expanded eligibility for the TPNIES under § 413.236 to include certain capital-related assets that are home dialysis machines when used in the home for a single patient. To establish the TPNIES basis of payment for these items, we finalized the additional steps that the Medicare Administrative Contractors (MACs) must follow to calculate a pre-adjusted per treatment amount, using the prices they establish under § 413.236(e) for a capital-related asset that is a home dialysis machine, as well as the methodology that CMS uses to calculate the average per treatment offset amount for home dialysis machines that is used in the MACs' calculation, to account for the cost of the home dialysis machine that is already in the ESRD PPS base rate. For purposes of this proposed rule, we will refer to this as the ''TPNIES offset amount.''

The methodology for calculating the TPNIES offset amount is set forth in § 413.236(f)(3). Section 413.236(f)(3)(v) states that effective January 1, 2022, CMS annually updates the amount determined in § 413.236(f)(3)(iv) by the ESRD bundled market basket percentage increase factor minus the productivity adjustment factor. The TPNIES for capital-related assets that are home dialysis machines is based on 65 percent of the MAC-determined pre-adjusted per treatment amount, reduced by the TPNIES offset amount, and is paid for 2 calendar years.

The proposed CY 2023 TPNIES offset amount for capital-related assets that are home dialysis machines is $9.73. As discussed previously in section II.B.1.a(3)(c) of this proposed rule, the proposed CY 2023 ESRD bundled market basket increase factor minus the productivity adjustment is 2.4 percent (2.8 percent minus 0.4 percentage point). Applying the proposed update factor of 1.024 to the CY 2022 offset amount results in the proposed CY 2023 offset amount of $9.73 ($9.50 × 1.024 = $9.73). We propose to update this calculation to use the most recent data available in the CY 2023 ESRD PPS final rule.

f. Proposed Revision to the Oral-Only Drug Definition and Clarification Regarding the ESRD PPS Functional Category Descriptions

(1) Background

Section 1881(b)(14)(A)(i) of the Act requires the Secretary to implement a payment system under which a single payment is made to a provider of services or a renal dialysis facility for renal dialysis services in lieu of any other payment. Section 1881(b)(14)(B) of the Act defines renal dialysis services,

and subclause (iii) of such section states that these services include other drugs and biologicals [14] that are furnished to individuals for the treatment of ESRD and for which payment was made separately under this title, and any oral equivalent form of such drug or biological.

When we implemented the ESRD PPS in 2011 (75 FR 49030), we interpreted this provision as including not only injectable drugs and biological products used for the treatment of ESRD (other than ESAs and any oral form of ESAs, which are included under clause (ii) of section 1881(b)(14)(B) of the Act), but also all oral drugs and biological products used for the treatment of ESRD and furnished under title XVIII of the Act. We also concluded that, to the extent oral-only drugs or biological products used for the treatment of ESRD do not fall within clause (iii) of section 1881(b)(14)(B) of the Act, such drugs or biological products would fall under clause (iv) of such section, and constitute other items and services used for the treatment of ESRD that are not described in clause (i) of section 1881(b)(14)(B) of the Act.

We finalized and promulgated the payment policies for oral-only renal dialysis service drugs or biological products in the CY 2011 ESRD PPS final rule (75 FR 49038 through 49053). In that rule we defined renal dialysis services at § 413.171 as including other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was made separately prior to January 1, 2011 under Title XVIII of the Act, including drugs and biologicals with only an oral form. Although we included oral-only renal dialysis service drugs and biologicals in the definition of renal dialysis services in the CY 2011 ESRD PPS final rule (75 FR 49044), we also finalized a policy to delay payment for these drugs under the ESRD PPS until January 1, 2014. In the CY 2011 ESRD PPS proposed rule (74 FR 49929), we noted that the only oral-only drugs that we identified were phosphate binders and calcimimetics, specifically, cinacalcet hydrochloride, lanthanum carbonate, calcium acetate, sevelamer hydrochloride, and sevelamer carbonate. All of these drugs fall into the ESRD PPS functional category for bone and mineral metabolism. In the CY 2011 ESRD PPS final rule (75 FR 49043), we explained that there were certain advantages to delaying the implementation of payment for oral-only drugs and biological products under the ESRD PPS, including allowing ESRD facilities additional time to make operational changes and logistical arrangements in order to furnish oral-only renal dialysis service drugs and biological products to their patients. Accordingly, we codified the delay in payment for oral-only renal dialysis service drugs and biological products at § 413.174(f)(6), and provided that payment to an ESRD facility for renal dialysis service drugs and biological products with only an oral form would be incorporated into the PPS payment rates effective January 1, 2014. Since oral-only drugs are generally not a covered service under Medicare Part B, this delay of payment under the ESRD PPS also allowed coverage to continue under Medicare Part D.

On January 3, 2013, ATRA was enacted. Section 632(b) of ATRA precluded the Secretary from implementing the policy under § 413.174(f)(6) relating to oral-only ESRD-related drugs in the ESRD PPS prior to January 1, 2016. Accordingly, in the CY 2014 ESRD PPS final rule (78 FR 72185 through 72186), we delayed payment for oral-only renal dialysis service drugs and biological products under the ESRD PPS until January 1, 2016. We implemented this delay by revising the effective date at § 413.174(f)(6) for providing payment for oral-only renal dialysis service drugs under the ESRD PPS from January 1, 2014 to January 1, 2016. In addition, we changed the date when oral-only renal dialysis service drugs and biological products would be eligible for outlier services under the outlier policy described in § 413.237(a)(1)(iv) from January 1, 2014 to January 1, 2016.

On April 1, 2014, PAMA was enacted. Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to preclude the Secretary from implementing the policy under § 413.174(f)(6) relating to oral-only renal dialysis service drugs and biological products prior to January 1, 2024. We implemented this delay in the CY 2015 ESRD PPS final rule (79 FR 66262) by modifying the effective date for providing payment for oral-only renal dialysis service drugs and biological products under the ESRD PPS at § 413.174(f)(6) from January 1, 2016 to January 1, 2024. We also changed the date in § 413.237(a)(1)(iv) regarding outlier payments for oral-only renal dialysis service drugs made under the ESRD PPS from January 1, 2016 to January 1, 2024. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by requiring that in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the most recent year available.

On December 19, 2014, ABLE was enacted. Section 204 of ABLE amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis services cannot be made under the ESRD PPS bundled payment prior to January 1, 2025. Similar to the CY 2014 and CY 2015 ESRD PPS final rule changes, we implemented this delay in the CY 2016 ESRD PPS final rule (80 FR 469028) by modifying the effective date for providing payment for oral-only renal dialysis service drugs and biological products under the ESRD PPS at § 413.174(f)(6) from January 1, 2024, to January 1, 2025. We also changed the date in § 413.237(a)(1)(iv) regarding outlier payments for oral-only renal dialysis service drugs made under the ESRD PPS from January 1, 2024 to January 1, 2025. We stated that we continue to believe that oral-only renal dialysis service drugs and biological products are an essential part of the ESRD PPS bundled payment and should be paid for under the ESRD PPS.

Section 217(c)(1) of PAMA required us to adopt a process for determining when oral-only drugs are no longer oral-only. In the CY 2016 ESRD PPS proposed rule (80 FR 37839), when considering a definition for the term ''oral-only drug,'' we noted that in the CY 2011 ESRD PPS final rule (75 FR 49038 through 49039), we described oral-only drugs as those that have no injectable equivalent or other form of administration. In the CY 2016 ESRD PPS final rule (80 FR 69027), we finalized the definition of oral-only drug at § 413.234(a) to provide that an oral-only drug is a drug or biological with no injectable equivalent or other form of administration other than an oral form. We also finalized our process at § 413.234(d) for determining that an oral only drug is no longer considered oral-only when a non-oral version of the oral-only drug is approved by FDA. We stated that we will undertake rulemaking to include the oral and any non-oral version of the drug in the ESRD PPS bundled payment when it is no longer considered an oral-only drug under this regulation. In addition, we noted that we will pay for the existing oral-only drugs (which were, at that time, only phosphate binders and calcimimetics) using the TDAPA, as applicable. We stated that this will allow us to collect data reflecting

[14] As discussed in the CY 2019 ESRD PPS final rule (83 FR 56922), we began using the term ''biological products'' instead of ''biologicals'' under the ESRD PPS to be consistent with FDA nomenclature. We use the term ''biological products'' in this CY 2023 ESRD PPS proposed rule except where referencing specific language in the Act or regulations.

current utilization of both the oral and injectable or intravenous forms of the drugs, as well as payment patterns and beneficiary co-pays, before we add these drugs to the ESRD PPS bundled payment. We also stated that for future oral-only drugs for which a non-oral form of administration comes on the market, we will apply our drug designation process as we would for all other new drugs.

In the CY 2016 ESRD PPS final rule (80 FR 69017), we also codified the term ESRD PPS functional category at § 413.234(a) as a distinct grouping of drugs and biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD. We explained that we codified this definition in regulation text to formalize the approach we adopted in CY 2011 because the drug designation process is dependent on the ESRD PPS functional categories (80 FR 69015). We provided a detailed discussion of how we accounted for renal dialysis drugs and biological products in the ESRD PPS base rate since the implementation of the ESRD PPS (80 FR 69013 through 69015). We discussed how we grouped renal dialysis drugs and biological products into functional categories based on their action (80 FR 37831). We explained that this was done for the purpose of adding new drugs and biological products with the same function into the functional categories and the ESRD PPS bundled payment as expeditiously as possible after the drug becomes commercially available to provide access for the ESRD Medicare population (80 FR 69014). Our approach of considering drugs and biological products as included in the ESRD PPS base rate if they fit within one of our ESRD PPS functional categories is reflected in the drug designation process set forth in our regulations at § 413.234.

In 2017, FDA approved an injectable calcimimetic. In accordance with the policy finalized in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027) described in the previous paragraphs, we issued a change request to implement payment under the ESRD PPS for both the oral and injectable forms of calcimimetics using the TDAPA.[15] We paid for calcimimetics using the TDAPA under the ESRD PPS for 3 years, CY 2018 through CY 2020, during which time CMS collected utilization data. In the CY 2021 ESRD PPS final rule (85 FR 71406 through 71410), we finalized a modification to the ESRD PPS base rate to account for the costs of calcimimetics following the methodology codified at § 413.234(f). Accordingly, effective January 1, 2021,[16] calcimimetics are no longer paid for using the TDAPA and instead are included in the ESRD PPS base rate. We also noted that effective January 1, 2021, calcimimetics are eligible for outlier payments as ESRD outlier services under § 413.237.[17]

At the present time, phosphate binders are still considered oral-only drugs, and therefore under current law will be paid under Medicare Part D until January 1, 2025, as long as they remain oral-only drugs. Beginning January 1, 2025, in accordance with § 413.174(f)(6), payment to an ESRD facility for renal dialysis service drugs and biologicals with only an oral form furnished to ESRD patients will be incorporated into the ESRD PPS and separate payment will no longer be provided.

Under our current policy (80 FR 69027), if an injectable equivalent or other form of administration of phosphate binders were to be approved by FDA prior to January 1, 2025, the phosphate binders would no longer be considered oral-only drugs and would no longer be paid outside the ESRD PPS. We would pay for the oral and any non-oral version of the drug using the TDAPA under the ESRD PPS for at least 2 years, during which time we would collect and analyze utilization data. If no other injectable equivalent (or other form of administration) of phosphate binders is approved by the FDA prior to January 1, 2025 then we would pay for these drugs using the TDAPA under the ESRD PPS for at least 2 years beginning January 1, 2025. CMS will then undertake rulemaking to modify the ESRD PPS base rate to account for the cost of the drug in the ESRD PPS bundled payment. As required by section 632(b)(1) of ATRA, as amended by section 217(a)(2) of PAMA, in establishing payment for oral-only drugs under the ESRD PPS, we will use data from the most recent year available.

(2) CMS Observations Regarding Decrease in Drug Utilization and Medicare Expenditures When Drugs Are Included in the ESRD PPS

As we prepare for the incorporation of oral-only drugs into the ESRD PPS bundled payment beginning January 1, 2025, we have been studying trends in drug utilization and Medicare expenditures for renal dialysis drugs and biological products. Our observations, presented below, provide further support for our longstanding view that oral-only renal dialysis service drugs and biological products are an essential part of the ESRD PPS bundled payment and should be paid for under the ESRD PPS.

With the transition of payment for calcimimetics from Medicare Part D to Medicare Part B, we observed two distinct patterns. First, when the calcimimetics were paid for using the TDAPA under the ESRD PPS beginning 2018, we observed a significant increase in the utilization of calcimimetics across patients of all races and ethnicities, with a more significant uptake by the African-American/Black minority population. As utilization increased, cost decreased. To demonstrate, before 2018, only brand-name oral calcimimetics were available, but in 2018, generic oral calcimimetics began to enter the market. We observed a greater than ten-fold decrease in the per milligram cost of Cinacalcet, the oral calcimimetic, from Q1 2018, which was the beginning of the TDAPA period for calcimimetics, and Q4 2020. We believe that the transition of payment for calcimimetics from Part D to Part B increased access for the population that lacked Part D coverage or had less generous coverage than the Part D standard benefit. Second, after we incorporated the calcimimetics into the ESRD PPS bundled payment beginning January 1, 2021, we noted a decrease in the calcimimetic utilization overall, with a pronounced decrease in the more expensive injectable calcimimetic. In order to mitigate the risk of potential access issues for minority populations, which include African-American/Black, Asian, Hispanic, and Other non-white populations, we believe it is important that any future oral-only drugs that fit into a current ESRD PPS functional category be included in the ESRD bundled payment through the processes previously finalized in our regulations at § 413.234 and described in this CY 2023 ESRD PPS proposed rule.

We have noted a similar pattern in the change in utilization with other renal dialysis service drugs, such as vitamin D agents, which were separately paid

[15] Change Request 10065, Transmittal 1889, issued August 4, 2017, replaced by Transmittal 1999, issued January 10, 2018, implemented the TDAPA for calcimimetics effective January 1, 2018.

[16] Change Request 12011, Transmittal 10568, issued January 14, 2021,

[17] In the CY 2020 ESRD PPS final rule (84 FR 60803), CMS made a technical change to § 413.234(a) to revise the definitions of ''ESRD PPS functional category'' and ''Oral-only drug'' to use the term ''biological product'' instead of ''biological'' for greater consistency with FDA nomenclature.

prior to the establishment of the ESRD PPS and subsequently included in the ESRD PPS bundled payment. Prior to the implementation of ESRD PPS, certain renal dialysis drugs and biological products were separately paid according to the number of units of the drug administered; in other words, the more units of a drug or biological product administered, the higher the Medicare payment.[18] Between 2011 and 2013, the first 3 years of the new ESRD PPS, the utilization of formerly separately billable renal dialysis drugs and biological products included in the ESRD PPS bundled payment declined. With the inclusion of the formerly separately billable renal dialysis drugs and biological products in the ESRD PPS bundled payment, the ESRD PPS increased the incentive for ESRD facilities to be more efficient in providing these products.

CMS has observed that incorporation of formerly separately billable renal dialysis drugs and biological products into the ESRD PPS bundled payment is followed by a decrease in utilization of the drug. For example, by drug class, on a per treatment basis, between 2007 and 2013, the use of vitamin D agents (part of the bone and mineral metabolism ESRD PPS functional category) declined by 20 percent, with most of the decline occurring between 2010 and 2013. Under the ESRD PPS, drug utilization and average sales price (ASP) data suggest increased competition between the two principal vitamin D agents in the ESRD PPS bundled payment. Between 2010 and 2014, per treatment use of paricalcitol, the costlier vitamin D drug (according to Medicare ASP data) declined, while per treatment use of doxercalciferol, the less costly vitamin D drug, increased. Between 2010 and 2015, the ASP price per unit for both these products declined by 60 percent. We have observed a similar pattern in price decline as a result of competition with the oral calcimimetics between 2018 and 2021. The brand name oral cinacalcet (a calcimimetic) was paid under Medicare Part D drug before 2018, but the price of the oral drug dropped significantly once the injectable calcimimetic became available and the oral (both brand name and generics) and the injectable calcimimetic became eligible for payment using the TDAPA under the ESRD PPS.

We have been monitoring health outcomes since 2011 and have not observed any sustained increase in adverse outcomes related to incorporation of renal dialysis drugs or biological products into the ESRD PPS bundled payment, including adverse outcomes related to changes in utilization of different forms of calcimimetics, as noted in the previous paragraph. To date, we have monitored for hospitalizations, fractures, strokes, acute myocardial infarctions, heart failures, parathyroidectomies, and calciphylaxis. Utilization of calcimimetics remains higher among minority populations, which include African-American/Black, Asian, Hispanic, and Other non-white populations, and we have not observed any sustained adverse health outcomes due to this change in utilization. We continue to monitor these health outcomes on an ongoing basis.

(3) CMS Observations on Part D Spending for Dialysis Drugs

While the use of formerly separately billable renal dialysis drugs included in the ESRD PPS bundled payment declined between 2011 and 2013, the use of dialysis drugs paid under Medicare Part D (as measured by Medicare spending) increased. Medicare Part D spending for oral-only drugs in 2016, which at that time only included calcimimetics and phosphate binders, grew to $2.3 billion, an increase of 22 percent per year compared with 2011. When calculated on a per treatment basis, Medicare Part D spending for dialysis drugs increased by 20 percent per year. In addition, between 2011 and 2016, total Medicare Part D spending for dialysis drugs grew more rapidly than total Medicare Part D spending for ESRD beneficiaries on dialysis (22 percent vs. 11 percent, respectively). In 2016, Medicare Part D spending for dialysis drugs constituted 60 percent of gross Medicare Part D spending for ESRD beneficiaries.

As noted previously in this section of the proposed rule, beginning on January 1, 2018, calcimimetics were paid for using the TDAPA under the ESRD PPS and beginning on January 1, 2021, were incorporated into the ESRD PPS bundled payment. Currently, phosphate binders are the only drugs that are paid for under Medicare Part D as oral-only drugs.

A number of studies, including studies by CMS, have examined trends in Medicare spending for phosphate binders. Between 2013 and 2014, Medicare Part D spending for phosphate binders increased by 24 percent to approximately $980 million. Medicare costs for phosphate binders for patients on dialysis and patients with chronic kidney disease enrolled in Medicare Part D exceeded $1.5 billion in 2015. Additionally, annual Medicare expenditures for phosphate binders increased by 118 percent (approximately $486 million) between 2008 and 2013, reflecting increasing numbers of patients on dialysis being prescribed phosphate binders and large increases in per-user phosphate binder costs. During these 6 years, total costs per user-year for phosphate binders increased 67 percent, in contrast to a 21 percent increase for all other Medicare Part D medications for patients receiving dialysis services.[19]

MedPAC has also studied Medicare spending under Part D for phosphate binders. According to MedPAC's report titled March 2021 Report to the Congress: Medicare Payment Policy [20] between 2017 and 2018, spending for phosphate binders furnished to FFS beneficiaries on dialysis declined by 17 percent to $1.1 billion. This decline is linked to FDA's approval in 2017 for a generic version of Renvela (sevelamer carbonate), a phosphate binder. By contrast, spending grew 12 percent per year for the five-year period 2012 through 2017. In 2018, Medicare Part D spending for phosphate binders accounted for 40 percent of all Medicare Part D spending for dialysis beneficiaries. The most recent CMS data through December 2020 indicates that total spending on phosphate binders is approximately $1 billion. The average spending per treatment of phosphate binders in 2020 is approximately $19.85 among all adult ESRD beneficiaries, and $24.24 among all Part D eligible adult ESRD beneficiaries. This illustrates that Medicare Part D spending for the same category of drugs is more expensive for ESRD beneficiaries with Medicare Part D.

MedPAC has also noted the benefits of the future incorporation of phosphate binders into the ESRD PPS bundled payment as of January 1, 2025. As noted in MedPAC's report titled March 2022 Report to the Congress: Medicare Payment Policy,[21] this is expected to result in better drug therapy management for the ESRD beneficiary, and to improve their access to these medications. MedPAC stated that this is especially important since some beneficiaries lack Part D coverage, or

[18] Report to the Congress: Medicare Payment Policy, March 2017. p. 169. *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar17_medpac_ch6.pdf.*

[19] Am J Kidney Dis 2018 Feb;71(2):246–253. doi: 10.1053/j.ajkd.2017.09.007. Epub 2017 Nov 28. CMS's data also confirms this figure.

[20] *https://www.medpac.gov/document/march-2021-report-to-the-congress-medicare-payment-policy/.*

[21] *https://www.medpac.gov/document/march-2022-report-to-the-congress-medicare-payment-policy/.*

have coverage less generous than the standard Part D benefit. MedPAC also noted that in addition to supporting equitable access for the ESRD beneficiaries, including phosphate binders in the ESRD PPS bundled payment might improve provider efficiency. MedPAC stated, and we have confirmed, that between 2018 and 2019, Medicare total spending increased for the phosphate binders that did not have generic competitors.

(4) The Oral-Only Drug Definition and ''Functional'' Equivalence Under the ESRD PPS

As noted previously in this section of the proposed rule, under § 413.234(a), we define an oral-only drug as ''A drug or biological product with no injectable equivalent or other form of administration other than an oral form.'' In addition, § 413.234(d) provides that an oral-only drug is no longer considered oral-only if an injectable or other form of administration of the oral-only drug is approved by the Food and Drug Administration. We note that there are various types of drug equivalences that are defined in regulation by FDA, including pharmaceutical equivalents, bioequivalents, and therapeutic equivalents.[22] However, we have not relied on these types of drug equivalences defined by FDA for purposes of the oral-only drug policy under the ESRD PPS.

Moreover, our regulations do not currently specify the meaning of the term ''equivalent'' in the definition of ''oral-only drug''.[23] We believe that the history of the ESRD PPS and our longstanding drug designation process indicate that CMS must consider ''functional'' equivalence, which is not described in FDA's regulations, in order to evaluate whether there is another form of administration other than an oral form and determine if a drug or biological product is an oral-only drug. For the purpose of ESRD PPS, we consider a drug or biological product to be functionally equivalent if it has the same end action effect as another renal dialysis drug or biological product. For example, when we first developed the Medicare ESRD PPS, we examined all renal dialysis drugs and biological products included in the prior composite rate payment system. Functional substitutes for those drugs or biological products were part of that evaluation. In the CY 2011 ESRD PPS final rule (75 FR 49044 through 49053) we explained our process for identifying drugs and biological products used for the treatment of ESRD that would be included in the ESRD PPS base rate. We performed an extensive analysis of Medicare payments for Part B drugs and biological products billed on ESRD claims and evaluated each drug and biological product to identify its category by indication or mode of action. We stated that categorizing drugs and biological products on the basis of drug action allows us to determine which categories (and therefore, the drugs and biological products within the categories) would be considered used for the treatment of ESRD (75 FR 49047).

In the CY 2016 ESRD PPS final rule, we codified our longstanding drug designation process at § 413.234 and reiterated that injectable and intravenous drugs and biological products were grouped into ESRD PPS functional categories based on their action (80 FR 69014). This was done for the purpose of adding new drugs or biological products with the same functions to the ESRD PPS bundled payment as expeditiously as possible after the drugs become commercially available so that beneficiaries have access to them. We further clarified that the ESRD PPS functional categories are not based on their mode of action, but rather end action effect (80 FR 69015 through 69017). Accordingly, and as noted previously in this section of this proposed rule, we finalized the definition of an ESRD PPS functional category in § 413.234(a) as a distinct grouping of drugs or biological products, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD (80 FR 69017 and 84 FR 60803).

Our guidance has also indicated that we consider functional equivalence when assessing whether particular drugs are renal dialysis services paid for under the ESRD PPS. The Medicare Benefit Policy Manual, Chapter 11, Section 20.3F states, ''Drugs that were used as a substitute for any of these drugs [that is, drugs that were considered composite rate drugs and not billed separately prior to the implementation of the ESRD PPS] or are used to accomplish the same effect are also covered under the composite rate.'' Given that we rely on functional equivalence in determining whether drugs are reflected in an ESRD PPS functional category and thus are renal dialysis services paid for under the ESRD PPS, we believe the same standard should apply when determining if a drug is an oral-only drug.

(5) Proposed Revision to the Definition of Oral-Only Drug

Based on our observations regarding renal dialysis drug utilization and spending and the upcoming changes related to payment for oral-only drugs under the ESRD PPS, we are proposing a change to the definition of oral-only drug at § 413.234(a). The current definition states that an oral-only drug is a drug or biological product with no injectable equivalent or other form of administration other than an oral form. We are proposing to modify the definition to specify that equivalence refers to functional equivalence, in line with our current drug designation process, which relies on the ESRD PPS functional categories. The proposed definition would state that an oral-only drug is a drug or biological product with no functional equivalent or other form of administration other than an oral form. We are proposing that this change would take effect beginning January 1, 2025, to coincide with the incorporation of oral-only drugs into the ESRD PPS bundled payment under § 413.174(f)(6).

We are proposing this change for several reasons. First, we note that it would be consistent with the policies previously established for phosphate binders and calcimimetics. As discussed previously in this section of the proposed rule, in the CY 2016 ESRD PPS final rule, we finalized that when a non-oral form of administration of a phosphate binder or calcimimetic is approved by FDA, we would go through rulemaking to include the oral and any non-oral form of administration of the drug in the ESRD PPS bundled payment. We explained that we would not take this approach for any subsequent drugs that are approved by FDA and fall within the bone and mineral metabolism functional category (or any other ESRD PPS functional categories). This is because the phosphate binders and calcimimetics were the only renal dialysis drugs for which we delayed payment under the ESRD PPS because we did not have utilization data (80 FR 69025). We believe that a revision to the oral-only drug definition to clarify that a drug is not an oral-only drug if it has a

[22] FDA has defined the terms ''pharmaceutical equivalents'', ''bioequivalence'', and ''therapeutic equivalents'' at 21 CFR 314.3(b). Therapeutic equivalence, as used in FDA's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations (see Section 1.21.15), applies only to drug products containing the same active ingredient(s) and does not encompass a comparison of different therapeutic agents used for the same condition. *https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.*

[23] Neither ATRA, PAMA, nor ABLE includes a definition of ''equivalent'' for purposes of the oral-only drug determination. Additionally, CMS did not provide a definition for or elaborate on the meaning of ''equivalent'' for purposes of the oral-only drug determination in our prior rules.

functional equivalent is consistent with that policy; that is, only oral-only drugs that are calcimimetics and phosphate binders would be eligible for a potential base rate addition and we would not take this approach for any subsequent drugs that fall within any of the ESRD PPS functional categories (80 FR 69025). While Congress has delayed the incorporation of oral-only drugs into the ESRD PPS until January 1, 2025, and this delay still applies to the phosphate binders as oral-only drugs, we believe we can still take action now to ensure that our drug designation process clearly reflects the longstanding ESRD PPS functional category framework.

In addition, this proposed modification would help ensure that we do not perpetuate any further delays in payment for renal dialysis services under the ESRD PPS. As noted previously, throughout the years, a series of legislative actions delayed the inclusion of oral-only drugs into the ESRD PPS bundled payment, from 2014 to 2016, to 2024, to January 1, 2025. When we first implemented the payment system in 2011, we noted that there were certain advantages to delaying payment for oral-only drugs under the ESRD PPS and continuing to pay for them under Part D, such as giving ESRD facilities additional time to make operational changes. CMS believes that sufficient time has passed since 2011 and we have abundant data about historical patterns to incorporate all drugs and biological products that are renal dialysis services into the ESRD PPS bundled payment as soon as possible under current law.

Our proposed modification would help ensure that new drugs and biological products that become available in the future and that are reflected in the ESRD PPS functional categories, are properly paid as part of the ESRD PPS. In other words, by specifying that an oral-only drug is one with no injectable ''functional'' equivalent, we would limit the scope of any new drugs or biological products that could be considered oral-only drugs in the future, and would therefore facilitate incorporation of these renal dialysis services into ESRD PPS. Any new oral renal dialysis drugs or biological products that are reflected in existing ESRD PPS functional categories and have functional equivalents in those categories would not meet the definition of an oral-only drug and thus could be included in the ESRD PPS bundled payment without delay, even if the functional equivalents are not ''chemical equivalents'' (that is, products containing identical amounts of the identical active drug ingredient). This would support beneficiary access to renal dialysis service drugs and would meet the intent of the ESRD PPS functional category framework, which is to be broad and to facilitate adding new drugs to the therapeutic armamentarium of the treating physician (83 FR 56941).

We note that over the past decade, CMS has been monitoring and analyzing data regarding beneficiary access to Medicare Part D drugs, Medicare expenditure increases for renal dialysis drugs paid under Medicare Part D, health equity implications of varying access to Medicare Part D drugs among patients with ESRD, and ESRD facility behavior regarding drug utilization. We have seen that incorporating Medicare Part D drugs into the ESRD PPS has had a significant positive effect of expanding access to such drugs for beneficiaries who do not have Medicare Part D coverage. As discussed earlier in this section of this proposed rule, this has significant health equity implications. For example, we have identified among these beneficiaries a significant uptake by the African-American/Black minority population for calcimimetics once we began paying for those drugs using the TDAPA under the ESRD PPS.

We believe the proposed modification of the oral-only drug definition would facilitate the inclusion of oral renal dialysis drugs into the ESRD PPS bundled payment, as opposed to payment under Medicare Part D, and therefore would support health equity for beneficiaries with oral-only drugs in their plan of care who lack Medicare Part D coverage, or have less generous than Medicare Part D standard benefit. From 2017 and 2021, between 10 to 20 percent of FFS beneficiaries on dialysis either had no Medicare Part D coverage or had coverage less generous than the Medicare Part D standard benefit. Timely inclusion of renal dialysis drugs and biological products into the ESRD PPS bundled payment would promote health equity for those beneficiaries who are not enrolled in Part D or who do not have access to these drugs through alternate insurance programs.

When compared with all FFS beneficiaries, FFS beneficiaries receiving dialysis are disproportionately young, male, disabled, and African-American, have low income as measured by dual status, and reside in an urban setting. We believe a clarification to help ensure that renal dialysis drugs and biological products are properly included in the ESRD PPS bundled payment would increase the likelihood of pharmaceutical compliance for this population of patients, promote health equity for patients that lack Medicare Part D coverage or have coverage less generous than the Part D standard benefit, and contribute to better clinical outcomes by leveling the playing field for all patients with ESRD. In addition, this proposal would support Executive Order 13985, Advancing Racial Equity and Support for Underserved Communities through the Federal Government (86 FR 7009), which addresses conducting an equity assessment in federal agencies, and determining whether new policies, regulations, or guidance documents may be necessary to advance equity in agency action and programs.

In summary, we believe that a proposed modification to the definition of oral-only drug to specify ''functional'' equivalence would be consistent with the current policy for oral-only drugs and the ESRD PPS functional category framework, would help ensure that new renal dialysis drugs and biological products are paid for under the ESRD PPS without delay, and would continue to support health care practitioners' decision-making to meet the clinical needs of their patients. Additionally, the proposed modification would promote health equity and support proper financial incentives for ESRD facilities, in keeping with our fiduciary responsibility to the Medicare Trust Funds. For all of these reasons, we are proposing to include the word ''functional'' in the definition of oral-only drug at § 413.234(a), so that the definition would be ''a drug or biological product with no injectable functional equivalent or other form of administration other than an oral form.'' We propose that this change would be effective January 1, 2025. We seek comments on this proposal.

(6) Proposed Revisions To Clarify the ESRD PPS Functional Category Descriptions

In the CY 2011 ESRD PPS final rule (75 FR 49044 through 49053), we discussed the extensive analysis of Medicare payments that we performed in order to identify drugs and biological products that are used for the treatment of ESRD and therefore meet the definition of renal dialysis services (defined at section 1881(b)(14)(B) of the Act and 42 CFR 413.171) that would be included in the ESRD PPS base rate. We analyzed Medicare Part B drugs and biological products billed on ESRD claims and evaluated each drug and biological product to identify its category by indication or mode of action. We also explained that categorizing drugs and biological products on the basis of drug action would allow us to determine which categories (and therefore, the drugs and

biological products within the categories) would be considered used for the treatment of ESRD (75 FR 49047).

Using this approach, we established categories of drugs and biological products that are not considered for the treatment of ESRD, categories of drugs and biological products that are always considered for the treatment of ESRD, and categories of drugs and biological products that *may* be used for the treatment of ESRD but are also commonly used to treat other conditions (75 FR 49049 through 49051). Those drugs and biological products that were identified as not used for the treatment of ESRD were not considered renal dialysis services and were not included in computing the ESRD PPS base rate. The categories of drugs and biologicals that were always considered used for the treatment of ESRD were identified as access management, anemia management, anti-infectives (specifically vancomycin and daptomycin used to treat access site infections), bone and mineral metabolism, and cellular management (75 FR 49050). In the CY 2015 ESRD PPS final rule, we removed anti-infectives from the list of categories of drugs and biological products that are included in the ESRD PPS base rate and not separately payable (79 FR 66149 through 66150). The categories of drugs that were considered always used for the treatment of ESRD have otherwise remained unchanged since we finalized them in the CY 2011 ESRD PPS final rule. The current categories of drugs that are included in the ESRD PPS base rate and that may be used for the treatment of ESRD but are also commonly used to treat other conditions are antiemetics, anti-infectives, antipruritics, anxiolytics, drugs used for excess fluid management, drugs used for fluid and electrolyte management including volume expanders, and pain management (analgesics) (79 FR 66150).

Although commenters requested that we list the specific ESRD-only drugs in the CY 2011 ESRD PPS final rule rather than specifying drugs and biological products used for the treatment of ESRD, we chose to identify drugs and biological products by functional category. We did not finalize a drug-specific list because we did not want to inadvertently exclude drugs that may be substitutes for drugs identified. We stated that using categories of drugs allows CMS to update the bundled ESRD PPS base rate accordingly as new drugs and biological products become available (75 FR 49050). Because there are many drugs and biological products that have multiple uses, and because new drugs and biological products are being developed, we stated that we did not believe that a drug-specific list would be beneficial (75 FR 49050).

However, we provided a list of the specific Part B drugs and biological products (75 FR 49205 through 49209) and the former Part D drugs that were included in the bundled ESRD PPS base rate (75 FR 49210). We emphasized that drugs or biological products furnished for the purpose of access management, anemia management, vascular access or peritonitis, cellular management and bone and mineral metabolism will be considered a renal dialysis service under the ESRD PPS and will not be eligible for separate payment. In addition, we noted that any drug or biological product used as a substitute for a drug or biological product that was included in the bundled ESRD PPS base rate would also be a renal dialysis service and would not be eligible for separate payment (75 FR 49050).

In the CY 2016 ESRD PPS final rule (80 FR 69024), we finalized the drug designation process in our regulations at § 413.234 as being dependent upon the ESRD PPS functional categories, consistent with our policy since the implementation of the ESRD PPS in 2011. We discussed the history of the ESRD PPS functional category approach and noted that we grouped the injectable and intravenous drugs and biological products into ESRD PPS functional categories for the purpose of adding new drugs or biological products with the same functions to the bundled ESRD PPS base rate as expeditiously as possible. We also stated that in previous regulations we referred to these categories as drug categories, however, we believe the term functional categories is more precise and better reflects how we have used the categories. We explained that CMS has designated several new drugs and biological products as renal dialysis services because they fit within the ESRD PPS functional categories, consistent with the process noted in CY 2011 ESRD PPS final rule.

As described more fully in the CY 2016 ESRD PPS final rule (80 FR 69023 through 69024), CMS established a TDAPA policy in our regulation at § 413.234 that is based on a determination as to whether or not a drug fits into an existing ESRD PPS functional category. We defined an ESRD PPS functional category in our regulation at § 413.234(a) as a distinct grouping of drugs or biological products, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD.

In addition, in the CY 2016 ESRD PPS final rule (80 FR 69017), we explained that commenters suggested changes to our descriptions of some of the ESRD PPS functional categories in the preamble of the CY 2016 ESRD PPS proposed rule to more precisely define the drugs that would fit into the categories. In particular, the commenters suggested changes to the anti-infective, pain management, and anxiolytic ESRD PPS functional categories to better describe how each of the categories relate to the treatment of ESRD in accordance with the statute. The commenters suggested that we remove language from the description of the antiemetic functional category to eliminate drugs used to treat nausea caused by the use of oral-only drugs because these drugs are paid outside the ESRD PPS bundled payment and are covered under a separate benefit category.

In response to these suggestions, in the CY 2016 ESRD PPS final rule, we moved the anti-infective functional group from the list of drugs always used for the treatment of ESRD to the list of drugs that may be used for the treatment of ESRD (80 FR 69017). We also adopted the commenters' recommendations regarding narrowing the functional categories to describe how the category relates to the treatment of ESRD. We explained that many of the commenters' recommendations were consistent with how we believe the categories should be defined and help to ensure that the drugs that fall into them are those that are essential for the delivery of maintenance dialysis. We presented the final ESRD PPS functional categories, as revised with suggestions from commenters, in Table 8B in the CY 2016 ESRD PPS final rule (80 FR 69018). In that CY 2016 ESRD PPS final rule table, we listed each ESRD PPS functional category and rationale for association, meaning the reason we included drugs in each category, with examples of drugs in certain categories. Table 8B also separated the functional categories into those that describe drugs always considered used for the treatment of ESRD and those that described drugs that may be used for treatment of ESRD.

In the CY 2019 ESRD PPS final rule (83 FR 56928) we discussed the current ESRD PPS functional categories as part of our final policy to expand the TDAPA to all new renal dialysis drugs and biological products without modifying the base rate for drugs in existing functional categories. We emphasized that the functional categories are deliberately broad in nature because, when a new drug becomes available, it is added to the therapeutic

armamentarium of the treating physician (83 FR 56941).

In 2021, a new antipruritic drug was granted marketing authorization by FDA. The new antipruritic drug was approved for a single indication, chronic kidney disease associated pruritus. The new antipruritic drug was approved for the ESRD PPS TDAPA in December 2021 and will receive the TDAPA from April 1, 2022 until March 31, 2024. The Change Request (CR) 12583 that established the TDAPA for Korsuva® (difelikefalin) was issued on March 15, 2022.[24] As stated in that CR, the drug qualifies for the TDAPA as a drug or biological product used to treat or manage a condition for which there is an existing ESRD PPS functional category, specifically, the antipruritic category. Because the new drug already fits within the antipruritic ESRD PPS functional category, the drug will receive the TDAPA for 2 years (§ 413.234(b)). After the TDAPA period, the drug will be considered included in the ESRD PPS bundled payment and there will be no modification to the base rate (§ 413.234(c)(1)(i)).

In this proposed rule, we are taking the opportunity to review the descriptions for the existing ESRD PPS functional categories and propose certain clarifications to ensure our descriptions are as clear as possible for potential TDAPA applicants and the public. These proposed revisions to the descriptions would be consistent with our current policies for the ESRD PPS functional categories and would not be changes to the categories themselves. As required by the definition in § 413.234(a), the drugs and biological products in the ESRD PPS functional categories are grouped by end action effect, and as we have stated in the past, the functional categories are deliberately broad by design to provide practitioners an array of drugs to use that meet the specific needs of the ESRD patient (83 FR 56941). In offering category descriptions, which we have also identified as rationales for association (80 FR 69015, 69016, and 69018), it has not been our intention to strictly define or limit drugs in any functional category but rather to broadly describe the renal dialysis drugs and biological products that are currently available and fall into the categories. We are proposing to make the following clarifications:

- Indicate that certain ESRD PPS functional categories may include, but are not limited to, drugs that have multiple clinical indications. For example, drugs and biological products in the anxiolytic functional category could have multiple clinical indications, and we are proposing to amend the description to reflect this understanding.
- Add the term ''biological products'' to the descriptions of several ESRD PPS functional categories, which currently refer only to ''drugs''.
- Update the examples provided in some category descriptions to describe the end-action effect of drugs or biological products included in that functional category.

These proposed clarifications to the descriptions of the ESRD PPS functional categories are shown in italics in Table 13 of this proposed rule.

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[24] *https://www.cms.gov/files/document/r11295CP.pdf.*

TABLE 13: Proposed Clarifications to ESRD PPS Functional Category Descriptions

Functional Category	*Description and Examples*
Access Management	Drugs/*biological products* used to ensure access by removing clots from grafts, reverse anticoagulation if too much medication is given, and provide anesthetic for access placement.
Anemia Management	Drugs/*biological products* used to stimulate red blood cell production and/or treat or prevent anemia. *Examples of drugs/biological products in this category include ESAs and iron.*
Bone and Mineral Metabolism	Drugs/*biological products* used to prevent/treat bone disease secondary to dialysis. *Examples of drugs/biological products in t*his category include phosphate binders and calcimimetics.
Cellular Management	Drugs/*biological products* used for deficiencies of naturally occurring substances needed for cellular management. This category includes levocarnitine.
Antiemetic	*Drugs/biological products* used to prevent or treat nausea and vomiting secondary to dialysis. Excludes antiemetics used in conjunction with chemotherapy as these are covered under a separate benefit category.
Anti-infectives	*Drugs/biological products u*sed to treat infections. May include antibacterial and antifungal drugs.
Antipruritic	Drugs/*biological products* in this *category are included for their action to* treat itching *secondary* to dialysis *but may have* multiple clinical indications.
Anxiolytic	Drugs/*biological products* in this *category* are included for the treatment of restless leg syndrome *secondary* to dialysis *but may* have multiple *clinical indications.*
Excess Fluid Management	Drugs/*biological products/*fluids used to treat fluid excess *or fluid* overload.
Fluid and Electrolyte Management Including Volume Expanders	Intravenous drugs/*biological products/*fluids used to treat fluid and electrolyte needs.
Pain Management	Drugs/*biological products* used to treat graft site pain and to treat pain medication overdose.

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C. Proposed Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) for CY 2023 Payment

1. Background

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), CMS established the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) under the ESRD PPS, under the authority of section 1881(b)(14)(D)(iv) of the Act, in order to support ESRD facility use and beneficiary access to these new technologies. We established this add-on payment adjustment to help address the unique circumstances experienced by ESRD facilities when incorporating new and innovative equipment and supplies into their businesses and to support ESRD facilities transitioning or testing these products during the period when they are new to market. We added § 413.236 to establish the eligibility criteria and payment policies for the TPNIES.

In the CY 2020 ESRD PPS final rule (84 FR 60650), we established in § 413.236(b) that for dates of service occurring on or after January 1, 2020, we will provide the TPNIES to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) has been designated by CMS as a renal dialysis service under § 413.171; (2) is new, meaning granted marketing authorization by the Food and Drug Administration (FDA) on or after January 1, 2020; (3) is commercially available by January 1 of the particular CY, meaning the year in which the payment adjustment would take effect; (4) has a Healthcare Common Procedure Coding System (HCPCS) application submitted in accordance with the official Level II HCPCS coding procedures by September 1 of the particular CY; (5) is innovative, meaning it meets the substantial clinical improvement criteria specified in the Inpatient Prospective Payment System

(IPPS) regulations at § 412.87(b)(1) and related guidance; and (6) is not a capital related asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired).

Regarding the innovation requirement in § 413.236(b)(5), in the CY 2020 ESRD PPS final rule (84 FR 60690), we stated that we will use the following criteria to evaluate substantial clinical improvement for purposes of the TPNIES under the ESRD PPS based on the IPPS substantial clinical improvement criteria in § 412.87(b)(1) and related guidance:

A new technology represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. First, CMS considers the totality of the circumstances when making a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries. Second, a determination that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries means one of the following:

- The new renal dialysis equipment or supply offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments; or
- The new renal dialysis equipment or supply offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods, and there must also be evidence that use of the new renal dialysis service to make a diagnosis affects the management of the patient; or
- The use of the new renal dialysis equipment or supply significantly improves clinical outcomes relative to renal dialysis services previously available as demonstrated by one or more of the following: (1) a reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; (2) a decreased rate of at least one subsequent diagnostic or therapeutic intervention; (3) a decreased number of future hospitalizations or physician visits; (4) a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; (5) an improvement in one or more activities of daily living; an improved quality of life; or (6) a demonstrated greater medication adherence or compliance; or,
- The totality of the circumstances otherwise demonstrates that the new renal dialysis equipment or supply substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries.

Third, evidence from the following published or unpublished information sources from within the United States or elsewhere may be sufficient to establish that a new renal dialysis equipment or supply represents an advance that substantially improves, relative to renal dialysis services previously available, the diagnosis or treatment of Medicare beneficiaries: Clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.

Fourth, the medical condition diagnosed or treated by the new renal dialysis equipment or supply may have a low prevalence among Medicare beneficiaries.

Fifth, the new renal dialysis equipment or supply may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new renal dialysis equipment or supply.

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), we also established a process modeled after IPPS's process of determining if a new medical service or technology meets the substantial clinical improvement criteria specified in § 412.87(b)(1). As we discussed in the CY 2020 ESRD PPS final rule (84 FR 60682), we believe it is appropriate to facilitate access to new and innovative equipment and supplies through add-on payment adjustments similar to the IPPS New Technology Add-On Payment and to provide stakeholders with standard criteria for both inpatient and ESRD facility settings. In § 413.236(c), we established a process for our announcement of TPNIES determinations and a deadline for consideration of new renal dialysis equipment or supply applications under the ESRD PPS. We will consider whether a new renal dialysis equipment or supply meets the eligibility criteria specified in § 413.236(b) and summarize the applications received in the annual ESRD PPS proposed rules. Then, after consideration of public comments, we will announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS in the ESRD PPS final rule. In the CY 2020 ESRD PPS final rule, we also specified certain deadlines for the application requirements. We noted that we would only consider a complete application received by February 1 prior to the particular CY. In addition, we required that FDA marketing authorization for the equipment or supply must occur by September 1 prior to the particular CY. We also stated in the CY 2020 ESRD PPS final rule (84 FR 60690 through 60691) that we would establish a workgroup of CMS medical and other staff to review the materials submitted as part of the TPNIES application, public comments, FDA marketing authorization, and HCPCS application information and assess the extent to which the product provides substantial clinical improvement over current technologies.

In the CY 2020 ESRD PPS final rule, we established § 413.236(d) to provide a payment adjustment for a new and innovative renal dialysis equipment or supply. We stated that the TPNIES is paid for two calendar years. Following payment of the TPNIES, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will become an eligible outlier service as provided in § 413.237.

Regarding the basis of payment for the TPNIES, in the CY 2020 ESRD PPS final rule, we finalized at § 413.236(e) that the TPNIES is based on 65 percent of the price established by the MACs, using the information from the invoice and other specified sources of information.

In the CY 2021 ESRD PPS final rule (85 FR 71410 through 71464), we made several changes to the TPNIES eligibility criteria at § 413.236. First, we revised the definition of new at § 413.236(b)(2) as within 3 years beginning on the date of the FDA marketing authorization. Second, we changed the deadline for TPNIES applicants' HCPCS Level II code application submission from September 1 of the particular CY to the HCPCS Level II code application deadline for biannual Coding Cycle 2 for durable medical equipment, orthotics, prosthetics, and supplies (DMEPOS) items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the CY. In

addition, a copy of the applicable FDA marketing authorization must be submitted to CMS by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website in order for the equipment or supply to be eligible for the TPNIES the following year. Third, we revised § 413.236(b)(5) to remove a reference to related guidance on the substantial clinical improvement criteria, as the guidance had already been codified.

Finally, in the CY 2021 ESRD PPS final rule, we expanded the TPNIES policy to include certain capital-related assets that are home dialysis machines when used in the home for a single patient. We explained that capital-related assets are defined in the Provider Reimbursement Manual (chapter 1, section 104.1) as assets that a provider has an economic interest in through ownership (regardless of the manner in which they were acquired). We noted that examples of capital-related assets for ESRD facilities are dialysis machines and water purification systems. We explained that, although we stated in the CY 2020 ESRD PPS proposed rule (84 FR 38354) that we did not believe capital-related assets should be eligible for additional payment through the TPNIES because the cost of these items is captured in cost reports, they depreciate over time, and are generally used for multiple patients, there were a number of other factors we considered that led us to consider expanding eligibility for these technologies in the CY 2021 ESRD PPS rulemaking. We explained that, following publication of the CY 2020 ESRD PPS final rule, we continued to study the issue of payment for capital-related assets under the ESRD PPS, taking into account information from a wide variety of stakeholders and recent developments and initiatives regarding kidney care. For example, we considered various HHS home dialysis initiatives, Executive Orders to transform kidney care, and how the risk of COVID–19 for particularly vulnerable ESRD beneficiaries could be mitigated by encouraging home dialysis.

After closely considering these issues, we proposed a revision to § 413.236(b)(6) in the CY 2021 ESRD PPS proposed rule to provide an exception to the general exclusion for capital-related assets from eligibility for the TPNIES for capital-related assets that are home dialysis machines when used in the home for a single patient and that meet the other eligibility criteria in § 413.235(b), and finalized the exception as proposed in the CY 2021 ESRD PPS final rule. We finalized the same determination process for TPNIES applications for capital-related assets that are home dialysis machines as for all other TPNIES applications; that we will consider whether the new home dialysis machine meets the eligibility criteria specified in § 413.236(b) and announce the results in the **Federal Register** as part of our annual updates and changes to the ESRD PPS. In accordance with § 413.236(c), we will only consider, for additional payment using the TPNIES for a particular CY, an application for a capital-related asset that is a home dialysis machine received by February 1 prior to the particular CY. If the application is not received by February 1, the application will be denied and the applicant is able to reapply within 3 years beginning on the date of FDA marketing authorization in order to be considered for the TPNIES, in accordance with § 413.236(b)(2).

In the CY 2021 ESRD PPS final rule, at § 413.236(f), we finalized a pricing methodology for capital-related assets that are home dialysis machines when used in the home for a single patient, which requires the MACs to calculate the annual allowance and the preadjusted per treatment amount. The pre-adjusted per treatment amount is reduced by an estimated average per treatment offset amount to account for the costs already paid through the ESRD PPS base rate.[25] We finalized that this amount will be updated on an annual basis so that it is consistent with how the ESRD PPS base rate is updated.

We revised § 413.236(d) to reflect that we would pay 65 percent of the pre-adjusted per treatment amount minus the offset for capital-related assets that are home dialysis machines when used in the home for a single patient.

We revised § 413.236(d)(2) to reflect that following payment of the TPNIES, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will be an eligible outlier service as provided in § 413.237, except a capital-related asset that is a home dialysis machine will not be an eligible outlier service as provided in § 413.237.

In summary, under the current eligibility requirements in § 413.236(b), CMS provides for a TPNIES to an ESRD facility for furnishing a covered equipment or supply only if the item: (1) has been designated by CMS as a renal dialysis service under § 413.171; (2) is new, meaning within 3 years beginning on the date of the FDA marketing authorization; (3) is commercially available by January 1 of the particular CY, meaning the year in which the payment adjustment would take effect; (4) has a complete HCPCS Level II code application submitted in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the CY; (5) is innovative, meaning it meets the criteria specified in § 412.87(b)(1); and (6) is not a capital-related asset, except for capital-related assets that are home dialysis machines.

We received three applications for the TPNIES for CY 2023. A discussion of these applications is presented below.

a. CloudCath Peritoneal Dialysis Drain Set Monitoring System (CloudCath System)

CloudCath submitted an application for the TPNIES for the CloudCath Peritoneal Dialysis Drain Set Monitoring System (CloudCath System) for CY 2023. According to the applicant, the CloudCath System is a tabletop passive drainage system that detects and monitors solid particles in dialysate effluent during peritoneal dialysis (PD)[26] treatments. Solid particles in dialysate effluent, manifesting itself as cloudy dialysate, may indicate that the patient has peritonitis, an inflammation of the peritoneum in the abdominal wall, usually due to a bacterial or fungal infection.[27] PD therapy is a common cause of peritonitis.[28] If left untreated, the condition can be life threatening.[29] We note that CloudCath previously submitted an application for the TPNIES for the CloudCath System for CY 2022, as summarized in the CY 2022 ESRD PPS proposed rule (86 FR 36343 through 36347), but withdrew that application prior to the issuance of the CY 2022 ESRD PPS final rule (86 FR 61889). As indicated in the CY 2022 ESRD PPS final rule (86 FR 61889), the applicant withdrew its application from consideration after the issuance of the CY 2022 ESRD PPS proposed rule

[25] The CY 2021 TPNIES offset amount was $9.32. The CY 2022 TPNIES offset amount is $9.50. CMS is proposing a CY 2023 TPNIES offset amount of $9.73, as discussed in section II.B.1.(e) of this proposed rule.

[26] Peritoneal Dialysis: Waste products pass from the patient's body through the peritoneal membrane into the peritoneal (abdominal) cavity where the bath solution (dialysate) is introduced and removed periodically. Medicare Benefit Policy Manual Chapter 11—End Stage Renal Disease (ESRD) (Rev. 257, 03–01–19).

[27] Mayo Clinic Staff, ''Peritonitis,'' June 18, 2020, available at: *https://www.mayoclinic.org/diseases-conditions/peritonitis/symptoms-causes/syc-20376247*.

[28] *Ibid.*

[29] *Ibid.*

because it did not receive FDA marketing authorization by July 6, 2021, which was the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services. Under § 413.236(c), an applicant for the TPNIES must receive FDA marketing authorization for its new equipment or supply by that deadline prior to the particular calendar year. Therefore, as we stated in the CY 2022 ESRD PPS final rule, the CloudCath System was not eligible for consideration for the TPNIES for CY 2022.

PD-related peritonitis is a major complication and challenge to the long-term success and adherence of patients on PD therapy.[30] The applicant stated that only about 12 percent of eligible patients are on PD therapy.[31] The applicant claimed that the risk of PD-related peritonitis, and the challenges to detect it, are the main reasons for these figures. The guidelines for diagnosis of PD-related peritonitis, as outlined by the International Society for Peritoneal Dialysis (ISPD), recommend that peritonitis be diagnosed when at least two of the following criteria are present: (1) the patient experiences clinical features consistent with peritonitis (abdominal pain and/or cloudy dialysate effluent); (2) the patient's dialysate effluent has a whole blood count (WBC) >100 cells/μL or >0.1 × 10/L with polymorphonuclear (PMN) cells >50 percent; and (3) positive dialysis effluent culture is identified.[32] Additionally, the guidelines recommend that PD patients presenting with cloudy effluent be presumed to have peritonitis and treated as such until the diagnosis can be confirmed or excluded.[33] Per the guidelines, this means that for patients undergoing PD treatments at home, it is recommended that they self-monitor for symptoms of peritonitis, cloudy dialysate and/or abdominal pain, and seek medical attention for additional testing and treatment upon experiencing any or both of these symptoms.

According to the applicant, despite the fact that peritonitis is highly prevalent, symptom monitoring is insensitive and non-specific, which can contribute to late presentation for medical attention and treatment. The applicant asserted that under the current standard of care, PD patients face the following challenges in detecting peritonitis. First, the applicant stated that patients' fluid observation has low compliance rates as it relies on patients' close examination of their own dialysate effluent during PD treatments, which often occur while patients are asleep. Second, the applicant noted that it can be difficult for patients to visually detect peritonitis in dialysate effluent using a ''newspaper test'' for cloudiness, and can be even more difficult to see when the fluid is drained into a toilet, where it is diluted by water. The applicant stated that, as a result of these challenges, patients with ESRD suffer unsatisfactorily high mortality and morbidity from peritonitis, as well as high rates of PD modality loss, meaning they must discontinue PD and begin a different type of dialysis treatment. Per the applicant, the CloudCath System addresses these challenges by detecting changes in dialysate effluent at much lower levels of particle concentrations than the amount needed to accumulate for visual detection by patients.

Per the applicant, the CloudCath System consists of three components: (1) drain set, (2) sensor, and (3) patient monitoring software. As explained in the application, the CloudCath System's drain set connects to a compatible PD cycler's drain line to enable draining and monitoring of dialysate effluent before routing the fluid to the drainage receptacle. Per the CloudCath System User Guide, included in the application, the CloudCath System is compatible with the following PD cyclers: Baxter Healthcare Home Choice PRO™, Baxter Healthcare AMIA™ Automated PD System, and Fresenius Liberty® Select Cycler. Per the applicant, once the CloudCath System is attached to a compatible cycler, the dialysate effluent runs through the drain set, through the CloudCath System's optical sensor. The applicant explained that the CloudCath System's optical sensor detects and monitors changing concentrations of solid particles in the dialysate effluent during each dialysis cycle and reports the concentrations in a turbidity score. Per the applicant, the CloudCath System will indicate whether dialysate effluent has normal turbidity and will notify the patient and/or health care professional if the dialysate effluent turbidity has exceeded the notification threshold set by the patient's dialysis provider. The applicant stated that the optical sensor's hardware and software components allow for data trending over time and remote monitoring by a health care professional.

(1) Renal Dialysis Service Criterion (§ 413.236(b)(1))

Regarding the first TPNIES eligibility criterion in § 413.236(b)(1), that the item has been designated by CMS as a renal dialysis service under § 413.171, monitoring for peritonitis is a service furnished to individuals for the treatment of ESRD that is essential for the delivery of maintenance dialysis, and therefore the CloudCath System would be considered a renal dialysis service under § 413.171.

(2) Newness Criterion (§ 413.236(b)(2))

With respect to the second TPNIES eligibility criterion in § 413.236(b)(2), that the item is new, meaning within 3 years beginning on the date of the FDA marketing authorization, the applicant stated that the CloudCath System received FDA marketing authorization on February 9, 2022. Therefore, the CloudCath System is considered new.

(3) Commercial Availability Criterion (§ 413.236(b)(3))

Regarding the third TPNIES eligibility criterion in § 413.236(b)(3), that the item is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect, the applicant stated that the CloudCath System is not currently commercially available but noted that it expects the CloudCath System will be commercially available immediately after receiving FDA marketing authorization. We do not have information as to whether the product became currently commercially available following the FDA marketing authorization on February 9, 2022. We seek comment on the CloudCath System's commercial availability.

(4) HCPCS Level II Application Criterion (§ 413.236(b)(4))

Regarding the fourth TPNIES eligibility criterion in § 413.236(b)(4) requiring that the applicant submit a complete HCPCS Level II code application by the HCPCS Level II application deadline of July 5, 2022, the applicant stated that it has not submitted an application yet, but intends to apply by the deadline.

(5) Innovation Criteria (§§ 413.236(b)(5) and 412.87(b)(1))

(a) Substantial Clinical Improvement Claims and Sources

With regard to the fifth TPNIES eligibility criterion under § 413.236(b)(5), that the item is

[30] Kam-Tao Li, Philip, et al., ''ISPD Peritonitis recommendations: 2016 Update on Prevention and Treatment,'' Peritoneal Dialysis International 2016; 36(5):481–508, June 9, 2016, available at: *http://dx.doi.org/10.3747/pdi.2016.00078.*

[31] Briggs, et al., ''Early Detection of Peritonitis in Patients Undergoing Peritoneal Dialysis: A Device and Cloud-Based Algorithmic Solution,'' unpublished report.

[32] Kam-Tao Li, Philip, et al., ''ISPD Peritonitis recommendations: 2016 Update on Prevention and Treatment,'' Peritoneal Dialysis International 2016; 36(5):481–508, June 9, 2016, available at: *http://dx.doi.org/10.3747/pdi.2016.00078.*

[33] *Ibid.*

innovative, meaning it meets the substantial clinical improvement criteria specified in § 412.87(b)(1), the applicant made two claims. First, the applicant asserted that the CloudCath System offers substantial clinical improvement over technologies currently available for the Medicare patient population by offering the ability to monitor changes in turbidity of peritoneal dialysate effluent through continuous remote monitoring in patients with ESRD receiving PD therapy earlier than the current standard of care. Per the applicant, by allowing the clinical standard of care to be initiated earlier, the use of the CloudCath System changes the management of peritonitis patients by enabling clinicians to both diagnose peritonitis and initiate antibiotic treatment earlier. Second, the applicant asserted that the CloudCath System offers substantial clinical improvement over existing technologies because the device's remote monitoring capabilities provides patients with oversight and increased confidence that should peritonitis occur, it will be detected more reliably than visual detection and earlier than the current standard of care, allowing for earlier diagnosis and treatment management. The applicant claimed that by alleviating the fear associated with peritonitis and providing this additional support and confidence to patients, the CloudCath System can enable patients to either switch to or remain on home–PD, ultimately improving quality of life.

The applicant submitted two studies on the technology in support of its substantial clinical improvement claims. First, the applicant included a preliminary, unpublished report by Briggs, et al. of a proof of principle observational study that tested the ability of the CloudCath System and its dialysate effluent monitoring algorithm to detect indicators of peritonitis.[34] The study consisted of 70 PD patients outside of the U.S. who had been on PD for a long interval of time (>10 days), and thus were at an increased risk of developing peritonitis. Out of the 64 PD patients whose data were included in the study, over 40 PD patients were receiving intermittent PD,[35] which is not commonly used in the U.S. The remainder of the study participants were receiving Continuous Ambulatory Peritoneal Dialysis (CAPD).[36] The report states that in the U.S., PD is generally performed in a modality called Continuous Cycling Peritoneal Dialysis (CCPD),[37] in which a cycler automatically administers multiple dialysis exchange cycles, typically while patients sleep. Samples were collected from patients' PD effluent drainage bags and measured in the CloudCath System against a proprietary Turbidity Score threshold value and also tested for reference laboratory measurements according to ISPD guidelines for WBC count and differential (>100 cells/μL, >50 percent PMN).[38] Regarding the Turbidity Score threshold value, the study set a score to determine if the effluent sample in the CloudCath System was infected or not; samples greater than or equal to the Turbidity Score threshold value would be classified as infected, and samples less than the Turbidity Score threshold value would be classified as non-infected. The crude sensitivity and specificity of the CloudCath System was 96.2 percent and 91.2 percent, respectively. A majority of false positives (44 of 77 samples) occurred among patients already receiving antibiotic treatment for peritonitis, and another 20 false positive reports occurred because the patient had elevated turbidity due to a cause other than peritonitis. The investigators subsequently removed samples from patients already receiving treatment for peritonitis, setting the sensitivity for detecting peritonitis using the CloudCath System at 99 percent and the specificity at 97.6 percent.

The second study the applicant submitted is the Prospective Clinical Study to Evaluate the Ability of the CloudCath System to Detect Peritonitis Compared to Standard of Care during In-Home Peritoneal Dialysis (CATCH).[39] The applicant stated that it initiated this ongoing single-arm, open-label, multi-center study to demonstrate that the CloudCath System is able to detect changes in turbidity associated with peritonitis in PD patients prior to laboratory diagnosis of peritonitis with a high degree of specificity and sensitivity. The target enrollment is 186 participants over 18 years of age using CCPD as their PD modality, with at least 2 exchanges per night.[40] Patients with active infection and/or cancer are excluded from the trial.[41] The primary endpoint is time of peritonitis detection by the CloudCath System (defined as two consecutive Turbidity Scores >7.0) as compared to laboratory evidence of peritonitis (defined as WBC count >100 cells/μL or >0.1 × 109/L with percentage of PMN >50 percent).[42] While the study is ongoing, the applicant included the study protocol and the first preliminary results with its application.[43] According to the applicant, the first preliminary results demonstrate that as of December 29, 2020, 132 participants were enrolled in the CATCH Study at 13 sites.[44]

Enrolled participants underwent an average of 4.5 dialysate exchanges per night.[45] The preliminary results indicated that, as of December 29, 2020, there have been 7 peritonitis events that met the ISPD peritoneal fluid cell counts and differentials standard.[46] According to the applicant, 5 of the 7 peritonitis events described in the CATCH study occurred after initial use

[34] Briggs, et al., ''Early Detection of Peritonitis in Patients Undergoing Peritoneal Dialysis: A Device and Cloud-Based Algorithmic Solution,'' unpublished report.

[35] Intermittent Peritoneal Dialysis (IPD)—Waste products pass from the patient's body through the peritoneal membrane into the peritoneal cavity where the dialysate is introduced and removed periodically by machine. Peritoneal dialysis generally is required for approximately 30 hours a week, either as three 10-hour sessions or less frequent, but longer, sessions. Medicare Benefit Policy Manual Chapter 11—End Stage Renal Disease (ESRD) (Rev. 257, 03–01–19).

[36] Continuous Ambulatory Peritoneal Dialysis (CAPD)—In CAPD, the patient's peritoneal membrane is used as a dialyzer. The patient connects a 2-liter plastic bag of dialysate to a surgically implanted indwelling catheter that allows the dialysate to pour into the beneficiary's peritoneal cavity. Every 4 to 6 hours the patient drains the fluid out into the same bag and replaces the empty bag with a new bag of fresh dialysate. This is done several times a day. Medicare Benefit Policy Manual Chapter 11—End Stage Renal Disease (ESRD) (Rev. 257, 03–01–19).

[37] Continuous Cycling Peritoneal Dialysis (CCPD)—CCPD is a treatment modality that combines the advantages of the long dwell, continuous steady-state dialysis of CAPD, with the advantages of automation inherent in intermittent peritoneal dialysis. The solution exchanges, are performed at nighttime and are performed automatically with a peritoneal dialysis cycler. Generally, there are three nocturnal exchanges occurring at intervals of 2½ to 3 hours. Upon awakening, the patient disconnects from the cycler and leaves the last 2-liter fill inside the peritoneum to continue the daytime long dwell dialysis. Medicare Benefit Policy Manual Chapter 11—End Stage Renal Disease (ESRD) (Rev. 257, 03–01–19).

[38] Kam-Tao Li, Philip, et al., ''ISPD Peritonitis recommendations: 2016 Update on Prevention and Treatment,'' Peritoneal Dialysis International 2016; 36(5):481–508, June 9, 2016, available at: *http://dx.doi.org/10.3747/pdi.2016.00078.*

[39] CloudCath, ''A Prospective Clinical Study to Evaluate the Ability of the CloudCath System to Detect Peritonitis Compared to Standard of Care during In-Home Peritoneal Dialysis (CATCH),'' Preliminary Clinical Study Report (NCT04515498), Jan 27, 2020.

[40] CloudCath, ''A Prospective Clinical Study to Evaluate the Ability of the CloudCath System to Detect Peritonitis Compared to Standard of Care during In-Home Peritoneal Dialysis (CATCH),'' Study Protocol (CC–P–001), June 24, 2020.

[41] *Ibid.*

[42] *Ibid.*

[43] CloudCath, ''A Prospective Clinical Study to Evaluate the Ability of the CloudCath System to Detect Peritonitis Compared to Standard of Care during In-Home Peritoneal Dialysis (CATCH),'' Preliminary Clinical Study Report (NCT04515498), Jan 27, 2020.

[44] *Ibid.*

[45] *Ibid.*

[46] *Ibid.*

of the CloudCath System, and all 5 of the peritonitis events were also detected by the CloudCath System.[47] In the 5 events, the CloudCath System detected peritonitis 44 to 368 hours prior to the time of detection from a clinical laboratory.[48] The CloudCath System also detected peritonitis 27 to 344 hours prior to participants presenting to the hospital or clinic with signs or symptoms of peritonitis.[49] The applicant stated that these results support the claim that the CloudCath System would enable diagnosis of peritonitis earlier than the current standard of care through turbidity monitoring. According to the applicant, in the remaining 2 peritonitis events, participants experienced peritonitis prior to initial use of the CloudCath System, however, the CloudCath System detected peritonitis upon initial use.

In addition to the studies on the technology, the applicant submitted an article by Muthucumarana, et. al. on the impact of time-to-treatment on clinical outcomes of PD-related peritonitis.[50] The article included data from the Presentation and the Time of Initial Administration of Antibiotics With Outcomes of Peritonitis (PROMPT) Study, a prospective multicenter study from 2012 to 2014 that observed symptom-to-contact time, contact-to-treatment time, defined as the time from health care presentation to initial antibiotic, and symptom-to-treatment time in Australian PD patients. One hundred sixteen patients participated in the survey.[51] Out of the sample size of 116 survey participants, there were 159 episodes of PD-related peritonitis. Of these, 38 patient episodes met the primary outcome of PD failure (defined as catheter removal or death) at 30 days.[52] The median symptom-to-treatment time was 9.0 hours in all patients, 13.6 hours in the PD-fail group, and 8.0 hours in the PD-cure group.[53] The study found that the risk of PD-failure increased by 5.5 percent for each hour of delay of administration of antibiotics once patients presented to a health care provider.[54] However, neither symptom-to-contact nor symptom-to-treatment was associated with PD-failure in non-adjusted analyses, and the time from presentation to a health care provider to treatment was only associated with PD-failure outcomes in multivariable-adjusted analyses in a subset of patients who presented to hospital-based facilities. In addition to the Muthucumarana et. al. article, the applicant cited to other studies that have found that antibiotic treatment should begin as soon as possible in order to effectively treat infections other than peritonitis. [55] [56] [57] Per the applicant, these articles on time-to-treatment demonstrate that the CloudCath System's ability to detect effluent changes substantially earlier improves the standard of care, enabling PD-related peritonitis diagnosis and antibiotic treatment earlier while decreasing the likelihood of PD-failure due to PD-related peritonitis.

The applicant also submitted letters of support from a nephrologist at an academic institution and the following ESRD patient advocacy groups: the American Kidney Fund, the American Association of Kidney Patients, and the International Society of Nephrology. The nephrologist's letter of support endorsed the CloudCath System's ability to detect peritonitis and enable clinicians to begin to treat the infection earlier, preventing hospitalizations and complications such as the abandonment of home dialysis. The nephrologist's letter also asserted that the CloudCath System helps address the challenge of peritonitis as the main reason for abandonment of PD for HD, and will encourage a greater number of patients to select PD as their dialysis modality of choice. The letters from the American Association of Kidney Patients and the International Society of Nephrology encouraged CMS to consider the CloudCath System's TPNIES application, explaining that the technology would have several benefits to patients, for example, by reducing peritonitis-related hospitalizations, increasing adherence to PD, and encouraging higher utilization of PD as a viable alternative to in-center HD. The American Kidney Fund's letter emphasized that peritonitis is a significant concern for PD patients [58] and requested CMS support of all efforts that ensure patients with ESRD undergoing PD treatments can quickly detect and treat infections.

As noted previously in this section of the proposed rule, the applicant previously submitted a TPNIES application for CY 2022, but withdrew its application. Compared to the CY 2022 application, the applicant updated the number of patients and sites that were enrolled in the CATCH study. In its CY 2022 application, the applicant reported that as of December 29, 2020, 132 patients were enrolled in the CATCH study at 15 sites. In its CY 2023 application, the applicant provided updated enrollment figures and stated that as of May 5, 2021, 185 patients were enrolled in the CATCH study at 15 sites.

In response to CMS' preliminary assessment of CloudCath's substantial clinical improvement claims in the CY 2022 ESRD PPS proposed rule, the applicant provided additional information to clarify how the CloudCath System fits into the current standard of care and how use of the CloudCath System affects the management of the patient. The applicant stated that the monitoring of changes in turbidity enabled by the CloudCath System does not require clinicians to deviate from their current diagnosis or treatment sequence, since sign and symptom monitoring is an already accepted trigger for subsequent clinical steps and patient management. However, per the applicant, the detection of turbidity does allow clinicians to evaluate patients earlier in this clinical pathway for diagnosis of peritonitis and antibiotic/antimicrobial treatment in accordance with the ISPD guidelines. The applicant further stated that earlier detection of turbidity would not impact appropriate diagnosis and treatment with respect to false positives and that, while a small number of patients in the Briggs et al. study showed a change in turbidity that ultimately resulted in a false positive for infection, these patients would not have received inappropriate use of antimicrobial therapy compared to the standard of care per ISPD guidelines. The applicant further stated that even though the CloudCath System may in some instances detect change in turbidity in patients without infection,

[47] *Ibid.*

[48] *Ibid.*

[49] *Ibid.*

[50] Muthucumarana, et al., ''The Relationship Between Presentation and the Time of Initial Administration of Antibiotics With Outcomes of Peritonitis in Peritoneal Dialysis Patients: The PROMPT Study.,'' Kidney Int Rep. 2016 Jun 11;1(2):65–72. doi: 10.1016/j.ekir.2016.05.003. PMID: 29142915; PMCID: PMC5678844.

[51] *Ibid.*

[52] *Ibid.*

[53] *Ibid.*

[54] *Ibid.*

[55] Gacouin, A. et al., ''Severe pneumonia due to Legionella pneumophila: prognostic factors, impact of delayed appropriate antimicrobial therapy,'' Intensive Care Medicine 28, 686–691 (2002), *https://doi.org/10.1007/s00134-002-1304-8.*

[56] Houck, PM. et al., ''Timing of antibiotic administration and outcomes for Medicare patients hospitalized with community-acquired pneumonia,'' Arch Intern Med. 2004 Mar 22;164(6):637–44. doi: 10.1001/archinte.164.6.637. PMID: 15037492.

[57] Lodise TP, et al., ''Outcomes analysis of delayed antibiotic treatment for hospital-acquired Staphylococcus aureus bacteremia,'' Clin Infect Dis. 2003 Jun 1;36(11):1418–23. doi: 10.1086/375057. Epub 2003 May 20. PMID: 12766837.

[58] Mehrotra, Rajnish et al., ''The Current State of Peritoneal Dialysis,'' Journal of the American Society of Nephrology 27: 3238–3252, 2016. doi: 10.1681/ASN.2016010112, available at: *https://jasn.asnjournals.org/content/jnephrol/27/11/3238.full.pdf?with-ds=yes.*

these patients would still be clinically evaluated for peritonitis diagnosis and eligibility for antimicrobial treatment by a clinician as per the existing standard of care with the change in turbidity. Therefore, the applicant asserted, the CloudCath System does not result in increased provision of unnecessary antimicrobial therapy, nor deviate from the ISPD guidelines in terms of antimicrobial treatment pattern.

(b) CMS Preliminary Assessment of Substantial Clinical Improvement Claims and Sources

After a review of the information provided by the applicant regarding the CloudCath System, we note the following concerns with regard to the substantial clinical improvement criteria under § 413.236(b)(5) and § 412.87(b)(1). We note that, consistent with § 413.236(c), CMS will announce its final determination regarding whether the CloudCath System meets the substantial clinical improvement criteria and other eligibility criteria for the TPNIES in the CY 2023 ESRD PPS final rule.

Because the applicant claims to offer the ability to diagnose a medical condition, PD-related peritonitis, earlier in a patient population than allowed by currently available methods, the applicant must also include evidence that use of the new technology to make a diagnosis affects the management of the patient, as required under the substantial clinical improvement criteria at § 412.87(b)(1)(ii)(B). Specifically, § 412.87(b)(1)(ii)(B) states that a determination that a technology represents substantial clinical improvement over existing technology means: the new medical service or technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods and there must also be evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient.

As we noted previously in the CY 2022 ESRD PPS proposed rule (86 FR 36346 through 36347), it is not clear to us whether the studies submitted demonstrate or examine the impacts of using the technology on patients with ESRD such that we can determine whether it represents an advance that substantially improves the treatment of Medicare beneficiaries compared to renal dialysis services previously available. We note that the studies submitted serve as ''proof of concept,'' as they are testing whether the CloudCath System detects turbidity in dialysate effluent that may indicate PD-related peritonitis, and whether they do so earlier than patient observation and a cell count test. However, the studies are limited in that they do not observe how the CloudCath System, in measuring the turbidity in dialysate effluent and doing so earlier than traditional self-monitoring, affects the management of the patient as required under the substantial clinical improvement criteria at § 412.87(b)(1)(ii)(B). For example, as part of the CATCH Study, investigators deactivated the notification capability of the CloudCath System for the duration of the study, so that neither the participants nor the investigators would be aware of the device measurements.[59] Therefore, as currently designed, the CATCH study may not examine patient and clinician behavior, including the medical management of the patient, after the CloudCath System detected the solid particles in the dialysate effluent. The Briggs et al. study also did not examine how use of the CloudCath System impacted management of the patient. The investigators in that study stated that none of the data from the device was used for clinical decision making, which indicates to us that the study did not test how or if the CloudCath System offered the ability to diagnose a medical condition and how use of the CloudCath System to make a diagnosis affected the management of the patient.[60] Because the studies submitted did not observe how patients and clinicians use the CloudCath System's monitoring to make decisions regarding patient management, it is unclear how they support a finding that early detection of PD-related peritonitis by the CloudCath System meets the substantial clinical improvement criteria at § 412.87(b)(1)(ii)(B).

Similarly, while the applicant submitted evidence to show that time-to-treatment plays a role in preventing PD failure in patients with ESRD with PD-related peritonitis,[61] CMS has not received information regarding how the CloudCath System would affect management of the patient by reducing time-to-treatment for patients with ESRD receiving PD therapy. CMS also notes that the applicant referenced studies that support beginning antibacterial therapy for infections other than PD-related peritonitis, like pneumonia, and therefore, do not directly demonstrate the importance of time-to-treatment for PD-related peritonitis.

As we noted in the CY 2022 ESRD PPS proposed rule, it is also not clear to us whether the CloudCath System would affect medical management of the patient because use of the technology may potentially detect turbidity changes in dialysate effluent so early, that, in some cases, health care providers may still decide to wait for confirmation via patient symptoms, cell count, or positive culture as stated in the ISPD guidelines on diagnosis.[62] It is unclear whether clinicians would begin treatment for peritonitis without observing patient symptoms, cloudy dialysate, or confirming cell count via fluid test or how turbidity information would be incorporated into clinical practice among physicians who may empirically treat asymptomatic patients with antibiotics while awaiting cell count and culture results to confirm a peritonitis diagnosis.

We note that the applicant stated that the first preliminary results of the CATCH study demonstrated that the CloudCath System detected PD-related peritonitis 33 to 367 hours prior to the time of detection from a clinical laboratory, and it also detected PD-related peritonitis 27 to 344 hours prior to participants presenting to a healthcare facility with symptoms of PD-related peritonitis. [63] [64] However, we note that no evidence was submitted to show that clinicians would begin to treat suspected peritonitis if the CloudCath System alerted the patient and clinician of possible PD-related peritonitis that was too early to detect via any of the ISPD guidelines.[65] In

[59] CloudCath, ''A Prospective Clinical Study to Evaluate the Ability of the CloudCath System to Detect Peritonitis Compared to Standard of Care during In-Home Peritoneal Dialysis (CATCH),'' Preliminary Clinical Study Report, NCT04515498, Jan 27, 2020.

[60] Briggs, et al., ''Early Detection of Peritonitis in Patients Undergoing Peritoneal Dialysis: A Device and Cloud-Based Algorithmic Solution,'' unpublished report.

[61] Muthucumarana, et. al., ''The Relationship Between Presentation and the Time of Initial Administration of Antibiotics With Outcomes of Peritonitis in Peritoneal Dialysis Patients: The PROMPT Study.,'' Kidney Int Rep. 2016 Jun 11;1(2):65–72. doi: 10.1016/j.ekir.2016.05.003. PMID: 29142915; PMCID: PMC5678844.

[62] Kam-Tao Li, Philip, et al., ''ISPD Peritonitis recommendations: 2016 Update on Prevention and Treatment,'' Peritoneal Dialysis International 2016; 36(5):481–508, June 9, 2016, available at: *http://dx.doi.org/10.3747/pdi.2016.00078.*

[63] CloudCath, ''A Prospective Clinical Study to Evaluate the Ability of the CloudCath System to Detect Peritonitis Compared to Standard of Care during In-Home Peritoneal Dialysis (CATCH),'' Preliminary Clinical Study Report (NCT04515498), Jan 27, 2020.

[64] *Ibid.*

[65] Kam-Tao Li, Philip, et al., ''ISPD Peritonitis recommendations: 2016 Update on Prevention and

Continued

other words, we have not received evidence to demonstrate that the CloudCath System would affect medical management of the patient by replacing one of the ISPD guidelines for diagnosis.[66] As two criteria are necessary for diagnosis of peritonitis (per ISPD guidelines noted by the applicant), it is unclear why the CloudCath System detection alone in the control arm (absent clinical manifestations such as symptomatic patients or cloudy effluent) is comparable as a diagnosis of peritonitis to patients with clinical manifestations plus laboratory evidence of peritonitis. In other words, we question whether a more appropriate comparison to demonstrate a time difference would be time to laboratory-confirmed peritonitis in both study arms, or time to antibiotic initiation following the CloudCath System notification versus antibiotic initiation following standard of care patient monitoring.

Further, we are concerned by the applicant's statements in response to the concerns we noted in the CY 2022 ESRD PPS proposed rule that the monitoring of changes in turbidity enabled by the CloudCath System does not require clinicians to deviate from their current diagnosis or treatment sequence. As stated previously, our regulations under § 412.87(b)(1)(ii)(B) require evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient. Therefore, we request information that demonstrates that the CloudCath System affects the management of the patient, including by impacting clinicians' diagnosis or treatment sequence.

While the applicant updated the CY 2023 application to include more patient and site enrollment, CMS has concerns that the CATCH trial is not designed to indicate potential changes in clinical practice in a way that would be helpful for substantial clinical improvement assessment. We welcome additional information regarding whether use of CloudCath has demonstrated lower hospitalization rates, an increase in PD use, or decrease in peritoneal dialysis modality loss, or improved mortality for our analysis. We also believe that any data on clinician and patient behavior while using the CloudCath System, for example by enabling CloudCath notifications or alarms in the CATCH Study, would be informative in our assessment.

Finally, regarding the applicant's claim that the CloudCath System's remote monitoring capabilities help to assure patients that peritonitis could be detected and treated earlier, and that by alleviating the fear of peritonitis, the CloudCath System enables patients to either switch to or remain on home-PD, ultimately improving quality of life, we are concerned there may be insufficient evidence to demonstrate that the CloudCath System improves patients' quality of life. The applicant referenced literature regarding health-related quality of life in home dialysis patients as well as information regarding the challenges of managing PD patients remotely. [67] [68] [69] However, we did not receive any data demonstrating improved quality of life or PD retention with the use of the CloudCath System, and we would be interested in additional evidence to support this claim.

We are inviting public comments on whether the CloudCath System meets the substantial clinical improvement criteria for the TPNIES.

(6) Capital-Related Assets Criterion (§ 413.236(b)(6))

Regarding the sixth TPNIES eligibility criterion in § 413.236(b)(6), limiting capital-related assets from being eligible for the TPNIES, except those that are home dialysis machines, the applicant stated that the CloudCath System is not a capital-related asset. We note that the CloudCath System does not meet the definition of a capital-related asset under § 413.236(a)(2), because it is not an asset that the ESRD facility has an economic interest in through ownership and is subject to depreciation.[70]

b. SunWrap™ System

Sun Scientific, Inc. submitted an application for the TPNIES for the SunWrap™ System for CY 2023. According to the applicant, the technology is comprised of a compression sleeve with a transparent air bladder and hand pump designed to provide static pneumatic compression to the forearm and/or upper arm following dialysis needle removal from the arteriovenous (AV) fistula access. The applicant explained that following hemodialysis (HD), gauze is placed over the puncture sites as the needles are removed, and then the SunWrap™ System is placed around the arm with the transparent bladder positioned over the gauze-covered access site. Per the applicant, the SunWrap™ System is then inflated, compressing the site to stop bleeding. Per the applicant, the SunWrap™ System provides a sufficient source of pressure to compress the AV intervention puncture site and has adjustable compression at 20–30mmHg and 30–40 mmHg. The applicant also stated that the inflation portion of the wrap is composed of completely transparent film, allowing for visualization of the puncture site(s) and ensuring that the hemostasis can be monitored. The applicant stated that the SunWrap™ System is easy to apply, safe, non-invasive, requires minimal training of only one tutorial, and has been proven to meet patient satisfaction and safety requirements after multiple trials.

The applicant also submitted a SunWrap™ System brochure noting that the product is indicated for post-HD treatment needle puncture management for hemostasis of needle site and that it is contraindicated for use directly on an open wound. The applicant submitted the following listing of the SunWrap™ System's line of products: Upper Arm—Right Small, Upper Arm—Right Large, Forearm Right, Upper Arm—Left Small, Upper Arm- Left Large, Forearm Left, and MINI—Single Site.

The applicant stated that the SunWrap™ System is meant to replace the current method of compression for bleeding control, which relies on the patient or skilled caregiver manually applying pressure to the puncture site for up to 15 minutes following HD. Per the applicant, inadequate or incorrect application of compression can result in discomfort, excessive bleeding, hematoma, fistula damage, and potentially even death. The applicant stated that use of the SunWrap™ System allows for more consistent application of compression, frees up the hands of the patient or skilled caregiver, and allows for simultaneous visual management of the needle site.

(1) Renal Dialysis Service Criterion (§ 413.236(b)(1))

Regarding the first TPNIES eligibility criterion in § 413.236(b)(1), that the item has been designated by CMS as a renal dialysis service under § 413.171, compression to the HD access site following dialysis needle removal is a

Treatment,'' Peritoneal Dialysis International 2016; 36(5):481–508, June 9, 2016, available at: *http://dx.doi.org/10.3747/pdi.2016.00078.*

[66] *Ibid.*

[67] Bonenkamp AA, van Eck van der Sluijs et al. Kidney Medicine, Health-Related Quality of Life in Home Dialysis Patients Compared to In-Center Hemodialysis Patients: A Systematic Review and Meta-analysis. Vol.2(2) P139–154.

[68] 25 Ronco C, Crepaldi C, Rosner MH (eds): Remote Patient Management in Peritoneal Dialysis. Contrib Nephrol. Basel, Karger, 2019, vol 197, pp I–VI.

[69] Hansson JH, Finkelstein FO. Kidney Med. 2020 Sep 1;2(5):529–531.

[70] See also CMS Provider Reimbursement Manual, Chapter 1, Section 104.1. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929.*

service that is furnished to individuals for the treatment of ESRD and essential for the delivery of maintenance dialysis, and therefore would be considered a renal dialysis service under § 413.171.

(2) Newness Criterion (§ 413.236(b)(2))

With respect to the second TPNIES eligibility criterion in § 413.236(b)(2), that the item is new, meaning within 3 years beginning on the date of the FDA marketing authorization, the applicant did not submit an FDA marketing authorization date but instead, indicated that the SunWrap™ System is considered FDA Class I Exempt. We note that under FDA regulatory scheme, Class I exempt status is determined by FDA, which maintains on its website the listing of devices exempt from the premarket notification (510(k)) requirements. As described on the FDA website, Class I devices present minimal potential for harm to the user and are often simpler in design than Class II or Class III devices. Examples include enema kits and elastic bandages.[71]

The applicant submitted the following information pertaining to Sun Scientific, Inc.'s registration and product classification: (1) a document labeled *Class I Exempt Documentation* and (2) listing, registration, and Firm Establishment Identifier (FEI) numbers for *SunWrap.* While the *Class I Exempt Documentation* lacked identifying product information such as the SunWrap™ System's product name(s) and date of the Class I Exempt status determination, we located supplemental information online. Sun-Scientific, Inc. is identified on the FDA website with Registration Number: 3008773774, FEI Number: 3008773774, and Owner/Operator Number: 10034866.[72] Twelve devices were identified with this Owner/Operator Number, but only the following two devices include the regulation number (880.5075) included in the application: Dressing, Compression—Aerowrap; SunWrap and Dressing, Compression—SunWrap.[73]

After a review of the information provided by the applicant, we note the following concerns with regard to the newness criterion under § 413.236(b)(2). Consistent with § 413.236(c), CMS will announce its final determination regarding whether the SunWrap™ System meets the newness criterion and other eligibility criteria for the TPNIES in the CY 2023 ESRD PPS final rule.

First, the applicant included a product brochure and product selection listing of 7 SunWrap™ System products and did not clearly indicate which of the 7 products are the subject of the CY 2023 TPNIES application. In addition, it is not clear whether the listing and registration numbers provided apply to all 7 products. We request that the applicant clarify these points.

Second, while the applicant stated that the Sun Wrap™ System is considered FDA Class I Exempt, as indicated in § 413.236(b)(2), to be eligible for the TPNIES, the applicant must apply within three years of the FDA marketing authorization date. While our primary concern is the lack of FDA marketing authorization, we also note that the applicant did not clearly indicate the date of Class I Exempt status. Therefore, it is unclear whether the SunWrap™ System's Class I Exempt status is within the three-year window.

We note that manufacturers of devices that fall into a category of exempted Class I devices are not required to submit to FDA a premarket notification and obtain FDA clearance before marketing the device in the U.S. However, the manufacturer is required to register its establishment and list its device with FDA.[74] Devices that receive FDA marketing authorization have met regulatory standards that provide a reasonable assurance of safety and efficacy for the devices. For exempt devices, FDA has determined that a premarket notification is not required to provide a reasonable assurance of safety and effectiveness for the devices. However, exempt devices still must comply with certain regulatory controls (known as ''general controls'') to provide a reasonable assurance of safety and effectiveness for such devices. Our intent in requiring applicants to receive FDA marketing authorization was to exclude devices that lack FDA marketing authorization. However, we welcome public comment on these issues.

(3) Commercial Availability Criterion (§ 413.236(b)(3))

Regarding the third TPNIES eligibility criterion in § 413.236(b)(3), that the item is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect, the applicant stated that the Sun Wrap™ System is currently commercially available.

(4) HCPCS Level II Application Criterion (§ 413.236(b)(4))

Regarding the fourth TPNIES eligibility criterion in § 413.236(b)(4) requiring that the applicant submit a complete HCPCS Level II code application by the HCPCS Level II application deadline of July 5, 2022, the applicant stated that it submitted that application on January 31, 2022.

(5) Innovation Criteria (§§ 413.236(b)(5) and 412.87(b)(1))

(a) Substantial Clinical Improvement Claims and Sources

With regard to the fifth TPNIES eligibility criterion under § 413.236(b)(5), that the item is innovative, meaning it meets the substantial clinical improvement criteria specified in § 412.87(b)(1), the applicant asserted that the use of the SunWrap™ System significantly improves clinical outcomes relative to the current standard of care, which it identified as reliance on the patient or a skilled caregiver manually applying pressure to the puncture site for up to 15 minutes following HD.

The applicant presented the following six substantial clinical improvement claims: (1) a reduction in at least one clinically significant adverse event; (2) a decreased rate of at least one subsequent diagnostic or therapeutic intervention; (3) a decreased number of future hospitalizations or physician visits; (4) a more rapid beneficial resolution of the disease process treatment; (5) an improvement in one or more activities of daily living; and (6) an improved quality of life.

Regarding the first claim, a reduction in at least one clinically significant adverse event, the applicant stated that the SunWrap™ System potentially reduces the incidence of hematoma, fistula stenosis/thrombosis, and Fatal Vascular Access Hemorrhage (FVAH).

Regarding the second claim, a decreased rate of at least one subsequent diagnostic or therapeutic intervention,

[71] Food & Drug Administration. Learn if a Medical Device Has Been Cleared by FDA for Marketing. Available at: *https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing.* Accessed on March 23, 2022.

[72] U.S. Food & Drug Administration. Establishment Registration & Device Listing. Sun-Scientific Inc. Available at: *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?rid=124922.* Accessed on March 29, 2022.

[73] U.S. Food & Drug Administration. Establishment Registration & Device Listing. Sun-Scientific Inc. Available at: *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&showList=1&establishmentName=&regNum=&StateName=&CountryName=&OwnerOperatorNumber=10034866&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establishmentType=&PAGENUM=10&SortColumn=EstablishmentName20%25ASC&RegistrationNumber=3008773774.* Accessed on March 29, 2022.

[74] Food & Drug Administration. Learn if a Medical Device Has Been Cleared by FDA for Marketing. Available at: *https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing.* Accessed on March 23, 2022.

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the applicant stated that the SunWrap™ System potentially reduces the incidence of ER visits, estimated at $10,000 per visit, ultrasound assessment, or interventions for stenosis or thrombosis. The applicant also stated that the SunWrap™ System potentially reduces the incidence of hospital admissions that are estimated at $15,000 or more per admission. The applicant further stated that incident cases of ESRD are reaching nearly 21,000 annually, and that vascular access complications account for 16 to 25 percent of hospital admissions.[75]

Regarding the third claim, a decreased number of future hospitalizations or physician visits, the applicant stated that the SunWrap™ System reduces ER visits due to bleeding and the potential for subsequent admission, saving approximately $10,000 per visit.[76] The applicant also stated that the SunWrap™ System reduces the need for revascularization due to stenosis/thrombosis.[77]

Regarding the fourth claim, a more rapid beneficial resolution of the disease process treatment, the applicant stated that the SunWrap™ System reduces the need for nurses to be tied up with manual compression therapy, maximizing their efforts around dialysis treatment. The applicant also stated that the SunWrap™ System adds a layer of assurance as patients transfer to home therapy, as compression is not reliant on patient or caregiver ability to provide compression consistent with care that occurs in the clinics. Per the applicant, the SunWrap™ System provides consistent compression to needle sites post-dialysis with the ability to visualize sites through a transparent window potentially reducing the incidence of unrecognized bleeding.

Regarding the fifth claim, an improvement in one or more activities of daily living, the applicant stated that the SunWrap™ System could increase comfort levels of patients in the home setting and could help reduce fatigue-related compression interruption, and allow some normal activity while ensuring post-dialysis compression is provided, resulting in potential for improved patient satisfaction.

Regarding the sixth claim, improved quality of life, the applicant stated that the SunWrap™ System allows the patient to become more autonomous and that the ability to have their hands free while stopping bleeding post-HD is beneficial. The applicant also stated that the potential reduction in fistula complications could improve quality of life on a broader scale.

The applicant did not provide direct links to the supporting materials for each of the six claims, but rather referred more broadly to several sources of information as evidence of demonstrating substantial clinical improvement, including a U.S. Centers for Disease Control and Prevention fact sheet on Chronic Kidney Disease (CKD),[78] case studies on fatal hemorrhage from HD vascular access sites,[79] and a case study of managing fistula complications in the Emergency Department.[80] The applicant stated that there are 786,000 annual ESRD patients, 71 percent are on dialysis and 29 percent have kidney transplants.[81] Referring to Gage, et. al., the applicant stated that 75 percent of AV fistulae and AV grafts required one or more interventions; stenosis and thrombosis were the most common complications diagnosed and treated (41 percent and 16 percent respectively); and that potential needle-related complications accounted for 6 percent of this data set.[82] The applicant also asserted that a review of standard and early cannulation graft literature reveals that HD complications are similar across the graft types. The applicant further noted that in retrospective review articles, infection, hematoma, pseudoaneurysm, and bleeding occur at rates of up to 26 percent, 24 percent, 15 percent, and 14 percent, respectively.

The applicant also included a summary of what it described as evidence from an unpublished pilot study involving 54 patients in two vascular access laboratory sites, 23 and 31 patients from each site, respectively who required intervention on their AV fistula or graft access site.[83] The applicant provided background information stating that patients require AV fistula or graft interventions for various reasons such as maintenance angioplasty, fistulogram, or thrombectomy. Per the applicant, the physician normally uses sutures to close the puncture site and after the procedure, the patients are monitored in the recovery room for a few hours before the sutures are removed or patients revisit the clinic for suture removal. The applicant stated that this suturing technique is frequently used because it is quick, straightforward, and has been the common practice. The applicant further indicated that suture removal poses a risk of infection. The applicant stated that during the study, the SunWrap™ System was applied for wound closure in place of suturing with an inflation pressure at 20—40 mmHg and hold-time at 20 to 30 minutes for most of the patients because most patients were punctured with a large note sheath size of 6—8 F. The applicant also stated that in ESRD facilities, the needle size is relatively smaller and less inflation pressure and shorter hold-times are needed to achieve hemostasis. As such, the applicant asserted that the SunWrap™ System could be safely applied in the ESRD facility setting without extensive training.

The applicant noted two reported cases of immediate post-operative bleeding; one reported case (fistula) of thrombosis at 48 to 72 hours post-operatively; and three reported cases (two fistula and one graft) of thrombosis 30 days post-operatively. The applicant stated that there were no reported cases of post-operative bleeding, infection, and pseudoaneurysm at 48 to 72 hours.

Per the applicant, the two cases of immediate post-operative bleeding were directly due to the SunWrap™ System.

[75] Simon, E. (2016). The dialysis patient: managing fistula complications in the emergency department. EMDocs. Available at: *http://www.emdocs.net/dialysis-patient-managing-fistula-complications-emergency-department/*. Accessed on March 17, 2022.

[76] Simon, E. (2016). The dialysis patient: managing fistula complications in the emergency department. EMDocs. Available at: *http://www.emdocs.net/dialysis-patient-managing-fistula-complications-emergency-department/*. Accessed on March 17, 2022.

[77] Ibid.

[78] Centers for Disease Control and Prevention. Chronic Kidney Disease in the United States, 2021. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2021. Available at: *https://www.cdc.gov/kidneydisease/pdf/Chronic-Kidney-Disease-in-the-US-2021-h.pdf*. Accessed on March 17, 2022.

[79] Jose, M., Marshall, M., Read, G., Lioufas, N., Ling, J., Snelling, P., Polkinghorne, K. (2017). Fatal dialysis vascular access hemorrhage. Am J Kidney Dis., 70(4), 570–575. Available at: *https://www.sciencedirect.com/science/article/pii/S0272638617307497*. Accessed on March 17, 2022.

[80] Simon, E. (2016). The dialysis patient: managing fistula complications in the emergency department. EMDocs. Available at: *http://www.emdocs.net/dialysis-patient-managing-fistula-complications-emergency-department/*. Accessed on March 17, 2022.

[81] Centers for Disease Control and Prevention. Chronic Kidney Disease in the United States, 2021. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2021. Available at: *https://www.cdc.gov/kidneydisease/pdf/Chronic-Kidney-Disease-in-the-US-2021-h.pdf*. Accessed on March 17, 2022.

[82] Gage SM, Reichert H. Determining the incidence of needle-related complications in hemodialysis access: We need a better system. J Vasc Access. 2021 Jul;22(4):521–532. doi: 10.1177/1129729820946917. Epub 2020 Aug 18. PMID: 32811335. Available at: *https://pubmed.ncbi.nlm.nih.gov/32811335/*Accessed on March 17, 2022.

[83] Summary points included in the application identified as: Sun-Wrap A Novel device for arteriovenous (AV) access hemostasis, Presented by Steven H.S. Tan, M.D. & Sundaram Ravikumar, M.D., FACS.

Per the applicant, the first case occurred during training in the initial phase of the study and there was no repetitive event after modification of the technique and timing of the application of the SunWrap™ System. We note that the applicant did not specify the way in which the technique or timing of applying the SunWrap™ System were modified. The applicant stated that the second case was due to two distant puncture sites that exceeded the coverage for the SunWrap™ System. Per the applicant, in patients with two puncture sites that measure more than 7.5 cm apart or if there is immediate bleeding, suturing is the treatment of choice.

The applicant stated that the thrombosis cases identified (one case at 48 to 72 hours post-operatively and three cases 30-days post-operatively) were not directly due to the SunWrap™ System. Per the applicant, the patients did not have any complications while on the SunWrap™ System and left the clinic safely after thorough monitoring in the recovery room. The applicant further stated that the patients underwent dialysis after the removal of the SunWrap™ System and asserted that the dialysis may have been the major contributing factor for the thrombosis.

(b) CMS Preliminary Assessment of Substantial Clinical Improvement Claims and Sources

After a review of the information provided by the applicant, we note the following concerns with regard to the substantial clinical improvement criteria under § 413.236(b)(5) and § 412.87(b)(1). Consistent with § 413.236(c), CMS will announce its final determination regarding whether the SunWrap™ System meets the substantial clinical improvement criteria and other eligibility criteria for the TPNIES in the CY 2023 ESRD PPS final rule.

The applicant stated that the SunWrap™ System has the potential to represent substantial clinical improvement. However, it is not clear whether or how the evidence submitted by the applicant supports the applicant's 6 substantial clinical improvement claims. It would be helpful for our evaluation if the applicant would directly link each claim to the relevant supporting information. The applicant provided summary points of a non-published, single pilot study of 54 patients treated with the SunWrap™ System at two vascular access laboratory sites. While the applicant provided a bullet-point summary of the study setting, complications, and a brief discussion of study data, the applicant did not provide details pertaining to study type, timeframe, patient demographics and endpoints. We note that this study appears to involve patients treated with the SunWrap™ System for the purpose of controlling bleeding following interventional procedures involving an AV fistula or graft and does not involve use of the SunWrap™ System following HD treatment in the ESRD facility setting. We question the extent to which this data would be generalizable to the ESRD facility setting and would be interested in any data pertaining to the use the SunWrap™ System for the purpose of controlling bleeding in the ESRD facility setting; specifically, at the needle puncture sites following HD.

We also note that the applicant stated that the SunWrap™ System provides static pneumatic compression to the forearm and/or upper arm with a gauze bandage, following dialysis needle removal from the AV fistula access. We request clarification as to whether the SunWrap™ System's indication for use is limited to patients with AV fistula access sites or if it is also indicated for use among patients with AV graft access sites.

The applicant identified 6 cases of post-operative complications within the pilot study, stating that two were directly due to the SunWrap™ System and that the 4 remaining cases were unrelated to the SunWrap™ System, but did not offer data to substantiate this statement. In addition, the applicant stated that the SunWrap™ System has met patient satisfaction and safety requirements after multiple trials, but did not provide specific information in support of this statement within the application. We would appreciate additional information regarding these trials, as well as any additional data demonstrating that the SunWrap™ System represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. For example, it would be useful to consider data comparing the SunWrap™ System's outcomes to outcomes of patients treated by manual compression at the puncture site following HD.

The applicant referred to the SunWrap™ Mini, stating that it targets single puncture sites and may be useful for achieving hemostasis for puncture sites which are more than 7.5 cm apart, may be easier to use in ESRD facilities, and is currently in its initial phase of study. As noted previously in this section of the proposed rule, the applicant provided a listing of 7 SunWrap™ System products. We request clarification as to which of the 7 SunWrap™ System products were included in the primary pilot study of 54 patients. We welcome public comment on these issues.

(6) Capital-Related Assets Criterion (§ 413.236(b)(6))

Regarding the sixth TPNIES eligibility criterion in § 413.236(b)(6), limiting capital-related assets from being eligible for the TPNIES, except those that are home dialysis machines, the applicant did not address this criterion within its application. However, because the SunWrap™ System is not an asset that the ESRD facility has an economic interest in through ownership and is subject to depreciation, it is not a capital related asset.[84]

c. THERANOVA 400 Dialyzer/ THERANOVA 500 Dialyzer (THERANOVA)

Baxter Healthcare Corporation (Baxter) submitted an application for the TPNIES for the THERANOVA 400 Dialyzer/THERANOVA 500 Dialyzer, collectively referred to as ''THERANOVA,'' for CY 2023. According to the applicant, THERANOVA is a new class of single-use dialyzer, featuring an innovative three-layer membrane structure that enables more comprehensive removal of certain harmful proteins known as large middle molecules (LMMs), while selectively maintaining essential proteins in the blood during hemodialysis (HD), compared to conventional low-flux and high-flux dialyzers. The applicant noted that the '400' and '500' denote differences in surface area. The applicant stated that THERANOVA is used with standard HD machines, like most other high-flux dialyzers, but has unique membrane properties that allow for enhanced removal of LMM uremic toxins contributing to disease burden (cardiovascular disease, development of inflammation, and other comorbidities) while retaining appropriate levels of beneficial molecules such as albumin, coagulation factors, and immunoglobulins. We note that Baxter previously submitted an application for the TPNIES for THERANOVA for CY 2021, as discussed in the CY 2021 ESRD PPS proposed rule (85 FR 42167 through 42177) and the CY 2021 ESRD

[84] 42 CFR 413.236(a)(2); CMS Provider Reimbursement Manual, Chapter 1, Section 104.1. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929.*

PPS final rule (85 FR 71444 through 71457).[85]

The applicant stated that THERANOVA is intended to treat kidney failure by expanded hemodialysis (HDx). The applicant noted that previous dialyzers were only able to remove toxins up to 25 kilodaltons (kDa), while HDx, enabled by the THERANOVA dialyzer, can remove molecules from 25 kDa to approximately 45 kDa. The applicant explained that patients with CKD have increasing difficulty removing these solutes as their kidneys fail. The applicant further explained that these non-protein bound uremic solutes can be divided into three main categories: (1) small molecules (SMs), <0.5 kDa, with effective removal by diffusion, (2) small and medium middle molecules (SMMMs), 0.5 − <25 kDa, with limited removal by diffusion, and (3) large middle molecules (LMMs), 25 − 60 kDa, which requires higher permeability membranes for effective and efficient removal.[86] The applicant noted that evidence to date demonstrates a strong link between LMMs and the development of different outcome-related morbidities, and that uremia related to the retention of SMMMs/LMMs is associated with inflammation and cardiovascular events.[87] [88] [89] The applicant stated that THERANOVA's innovative hollow fiber, medium cut-off (MCO) membrane shows a permeability profile close to that of the natural kidney and expands the range of uremic toxin removal beyond what is achieved with current membranes during regular HD.

The applicant asserted that the design of THERANOVA allows for use on any HD machine, both in-center and home, made by Baxter or another manufacturer, by merely changing the dialyzer. The applicant stated that the membrane is compatible with standard fluid quality and does not require any additional fluid quality control measure.[90]

(1) Renal Dialysis Service Criterion (§ 413.236(b)(1))

With respect to the first TPNIES eligibility criterion under § 413.236(b)(1), whether the item has been designated by CMS as a renal dialysis service under § 413.171, maintenance dialysis treatments and all associated services, including historically defined dialysis-related drugs, laboratory tests, equipment, supplies, and staff time, were included in the composite rate for renal dialysis services as of December 31, 2010 (75 FR 49036). A dialyzer would be considered a supply essential for the delivery of maintenance dialysis and, therefore, we would consider this a renal dialysis service under § 413.171.

(2) Newness Criterion (§ 413.236(b)(2))

With respect to the second TPNIES eligibility criterion under § 413.236(b)(2), whether the item is new, meaning within 3 years beginning on the date of the FDA marketing authorization, the applicant stated that the THERANOVA received FDA marketing authorization for home use on August 28, 2020. Therefore, the THERANOVA is considered new.

(3) Commercial Availability Criterion (§ 413.236(b)(3))

With respect to the third TPNIES eligibility criterion under § 413.236(b)(3), whether the item is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect, the applicant stated that THERANOVA is commercially available in the U.S.

(4) HCPCS Level II Application Criterion (§ 413.236(b)(4))

With respect to the fourth TPNIES eligibility criterion under § 413.236(b)(4), whether the applicant submitted a HCPCS Level II code application by the July 5, 2022 deadline, the applicant stated a HCPCS application was submitted on June 27, 2020, and it intends to resubmit a HCPCS Level II code application by the July 5, 2022 deadline.

(5) Innovation Criteria (§§ 413.236(b)(5) and 412.87(b)(1))

(a) Substantial Clinical Improvement Claims and Sources

With respect to the fifth TPNIES eligibility criterion under § 413.236(b)(5), that the item is innovative, meaning it meets the substantial clinical improvement criteria specified in § 412.87(b)(1), the applicant asserted that THERANOVA significantly improves clinical outcomes relative to the current standard of care for dialysis membranes. The applicant presented the following substantial clinical improvement claims: (1) decrease in the number of future hospitalization by up to 45 percent; (2) improved recovery time by up to 2 hours; (3) improved quality of life (QoL) as indicated by reduced pruritus, improvement in two Kidney Disease Quality of Life (KDQoL) survey domains, and improved London Evaluation of Illness (LEVIL) scores; (4) reduced restless leg syndrome by 10 percent or more; and (5) reduced rate of subsequent therapeutic interventions such as reduced need for and use of erythropoietin stimulating agents (ESAs), iron, and insulin. The applicant supported these claims with seven published papers, one paper accepted for publication, and one poster. Several of the studies were secondary analyses of the same trial data.

With respect to the claim that THERANOVA decreases the number of future hospitalizations, the applicant noted that emergent need for hospitalization can be a serious and life-threatening event, especially for medically-fragile populations, and that hospitalization is a frequent and costly occurrence for the ESRD population. The applicant stated that an estimated 792,643 HD patient hospitalizations occur every year,[91] with roughly 40 percent of new dialysis patients averaging nearly two hospitalizations per year.[92] The applicant also asserted that ESRD patients often have health impairments associated with their condition and other comorbidities that put them at greater risk for

[85] As noted in the CY 2021 ESRD PPS final rule, we did not find the submitted evidence and public comments sufficient in meeting the substantial clinical improvement ''totality of the circumstances'' criterion at § 412.87(b)(1)(i). Therefore, we determined that THERANOVA did not qualify for the TPNIES at that time (85 FR 71457).

[86] Baxter. Theranova 400/500 Instructions For Use. N50 648 rev 003, 2017–05–29.

[87] Yilmaz MI, Carrero JJ, Axelsson J, Lindholm B, Stenvinkel P: Low-grade inflammation in chronic kidney disease patients before the start of renal replacement therapy: sources and consequences. Clin Nephrol 68:1– 9, 2007.

[88] Stenvinkel P. Can treating persistent inflammation limit protein energy wasting? Semin Dial. 2013;26(1):16–19. doi:10.1111/sdi.12020.

[89] Akchurin OM, Kaskel Fl. *Update on inflammation in chronic kidney disease.* Blood Purif 2015; 39:84–92.

[90] Alvarez L, et al. Intradialytic Symptoms and Recovery Time in Patients on Thrice-Weekly In-Center Hemodialysis: A Cross-sectional Online Survey, Kidney Med. 2020;2(2)125–130.

[91] The applicant's information on the number of hospitalizations is based on a Moran Company analysis of the following sourced figure: 'Average hospitalization rate' of hemodialysis patients captured from the United States Renal Data System (USRDS), 2020 Annual Data Report (ADR), End Stage Renal Disease, Chapter 4: Hospitalization, Figure 4.1a Adjusted hospitalization rates in prevalent Medicare beneficiaries with ESRD by treatment modality, 2009–2018.

[92] Nissenson AR, Improving Outcomes for ESRD Patients: Shifting the Quality Paradigm. CJASN Feb 2014, 9 (2) 430–434; DOI: 10.2215/CJN.05980613 *https://doi.org/10.2215/CJN.05980613.*

hospitalization, and at greater risk for adverse outcomes once hospitalized. The applicant stated that, for example, a recent study found that hospitalized ESRD patients on maintenance dialysis had higher odds of mortality after cardiopulmonary resuscitation (odds ratio, 1.24; 95 percent CI, 1.11 to 1.3; p < 0.001), compared to the general patient population.[93] The applicant explained that the frequency and severity of hospitalizations in the ESRD patient population adds urgency to adopting innovative technologies that can help prevent hospitalization and associated morbidity and mortality.

To support its claim that the use of THERANOVA decreases the number of future hospitalizations, the applicant referred to a poster by Tran et al. (2021), which was an abstract of a secondary analysis of a prospective, open-label, randomized controlled trial[94] of 172 patients (86 THERANOVA; 85 high-flux HD (HF–HD), with 1 patient not treated). As a post hoc analysis of a randomized controlled trial, the applicant stated that the objective of the study was to evaluate the association of HDx with the THERANOVA dialyzer with hospitalization rates, as compared to conventional HD. The applicant stated that patients were randomized and treated with either Theranova 400 or a conventional high-flux dialyzer in 21 U.S. study centers. The applicant noted that hospitalization was defined by the occurrence of any serious adverse event containing a hospitalization admission date, hospitalization rate was defined by treatment as total number of hospitalizations divided by total person-years of follow-up, and hospital length of stay was defined as number of days between admission and discharge. The applicant stated that this study found that the rate of hospitalizations for patients using THERANOVA was statistically significantly lower—45 percent—than those using HF–HD (IRR = 0.55; p = 0.0495).[95]

The applicant also referred to a multi-center, observational retrospective, cohort study by Molano-Triviño et al. (2022) that used propensity score matching assignment methods for 1,098 patients (534 HF–HD; 564 HDx with THERANOVA). The applicant stated that the objective of the study was to evaluate clinical effectiveness of THERANOVA versus HF–HD dialyzers, in terms of hospitalization rate and duration, cardiovascular event rate and survival in a HD cohort in Colombia. The applicant stated that adult HD patients (>90 days in HD) at Baxter Renal Care Services Colombia were included between September 1, 2017 to November 30, 2017, with follow-up until 2 years. The applicant noted that inverse probability of treatment weighting on the propensity score was used to balance comparison groups on indicators of baseline socio-demographic and clinical characteristics, and that the investigators compared rates and duration of hospitalization and cardiovascular events using a negative binomial regression to estimate weighted incidence rate ratios (IRRs). The applicant stated that this study found a statistically significant lower hospitalization rate in the THERANOVA group, compared to the HF–HD group (IRR HDx with THERANOVA/HF–HD: 0.82, 95 percent CI 0.69 to 0.98; p=0.03), without differences in hospitalization duration or survival.[96]

The applicant also referred to two other papers to further support reductions in hospitalization and medication utilization. According to the applicant, Sanabria et al. (2021) was a multi-center, observational prospective cohort study of 81 patients (Year 1, HF–HD; Year 2, HDx with THERANOVA). In this study across 3 clinics, the applicant noted that 175 patients with ESRD on chronic HD were originally recruited, and 23 did not meet the eligibility criteria. The applicant stated that patients received HF–HD for at least 1 year and then switched to HDx and were followed up for 1 year. The applicant stated that patients were excluded if they discontinued therapy, changed provider, underwent kidney transplant, recovered kidney function, or changed to PD, another dialyzer, or another renal clinic. The applicant noted that only 81 patients were eligible for analysis because 71 patients were lost to follow-up. The applicant asserted that the study results demonstrated that the rate of hospitalizations per patient-year was lower twelve months after switching to HDx, from 0.77 (95 percent CI: 0.60–0.98, 61 events) to 0.71 (95 percent CI: 0.55–0.92, 57 events), p=0.6987. The applicant also reported that the study results demonstrated significantly reduced hospital day rate per patient-year, from 5.94 days in the year prior to switching compared with 4.41 days after switching (p=0.0001).[97]

The applicant also cited Ariza et al. (2021), which the applicant noted analyzed the same study sample of 81 patients as Sanabria et al. (2021),[98] discussed previously in this section, with the stated objective of examining new evidence linking HDx using THERANOVA with hospitalizations, hospital days, medication use, costs, and patient utility. The applicant stated that this retrospective study utilized data from the Renal Care Services medical records database in Colombia from 2017 to 2019. The applicant noted that the study data included years on dialysis, hospitalizations, medication use, and QoL measured by the KDQoL survey at the start of HDx, and 1 year after HDx. The applicant stated that generalized linear models were run comparing patients before and after switching to HDx. The applicant asserted that the study results demonstrated that HDx was also significantly associated with lower hospital days per year (5.94 on HD vs. 4.41 on HDx), although not with the number of hospitalizations. The applicant stated that the results showed that HDx was statistically significantly associated with reduced hospitalization days.[99]

With respect to the claim that THERANOVA is associated with improved recovery time by up to 2 hours, the applicant stated that the treatment intensity and recovery time for patients on HD is a significant burden. The applicant explained that patients might receive in-center HD 3 days a week for 3 to 5 hour sessions, or home HD. The applicant noted that following treatment, there is often a prolonged period before a patient recovers to pre-treatment function and energy levels, with many patients reporting that they feel tired and in need

[93] Saeed F, Adil MM, Malik AA, Schold JD, Holley JL, Outcomes of In-Hospital Cardiopulmonary Resuscitation in Maintenance Dialysis Patients. JASN Dec 2015, 26 (12) 3093–3101; DOI: 10.1681/ASN.2014080766 *https://doi.org/10.1681/ASN.2014080766.*

[94] Weiner D, et al. Efficacy and Safety of Expanded Hemodialysis with the Theranova 400 Dialyzer: A Randomized Controlled Trial, CJASN15: 1310–1319, 2020. doi: 10.2215/CJN.01210120.

[95] Tran H, Falzon L, Bernardo A, Beck W, Blackowicz M. Reduction in all-cause Hospitalization Events Seen in a Randomized Controlled Trial Comparing Expanded Hemodialysis vs High-Flux Dialysis. Annual Dialysis Conference. Abstract #1070. Published 2021 Jan 28.

[96] Molano AP, Hutchison CA, Sanchez R, Rivera AS, Buitrago G, Dazzarola MP, Munevar M, Guerrero M, Vesga JI, Sanabria M, Medium Cut-Off Versus High-Flux Hemodialysis Membranes and Clinical Outcomes: A Cohort Study Using Inverse Probability Treatment Weighting, Kidney Medicine (2022), doi: *https://doi.org/10.1016/j.xkme.2022.100431.*

[97] Sanabria RM, Hutchison CA, Vesga JI, Ariza JG, Sanchez R, Suarez AM. Expanded Hemodialysis and Its Effects on Hospitalizations and Medication Usage: A Cohort Study. Nephron 2021;145:179–187. doi: 10.1159/000513328.

[98] Ibid.

[99] Ariza, JG, Walton, SM, Suarez, AM, Sanabria, M, Vesga, JI. An initial evaluation of expanded hemodialysis on hospitalizations, drug utilization, costs, and patient utility in Colombia. Ther Apher Dial. 2021; 25: 621– 627. *https://doi.org/10.1111/1744-9987.13620.*

of rest or sleep. The applicant cited an estimate that 40 to 80 percent of patients receiving chronic HD face post-dialysis fatigue.[100] The applicant also noted that patients who were highly fatigued had a significantly higher risk of adverse cardiovascular events (hazard ratio: 2.17; p <0.01).[101] The applicant referred to the Dialysis Outcomes and Practice Patterns Study (DOPPS), which analyzed over 6,000 HD patients from 12 countries in Europe, Japan, Canada, and the U.S. The applicant noted that 25 percent of patients required more than 6 hours of recovery time, and that patient-reported recovery time was positively associated with rates of first hospitalization (adjusted hazard ratio [AHR] per additional hour of recovery time [RT], 1.03; 95 percent CI, 1.02–1.04) and all-cause mortality (AHR, 1.05; 95 percent CI, 1.03–1.07).[102] The applicant stated that improving recovery time is not only critical to averting hospitalization and increased risk of mortality, but also ensures that ESRD patients have meaningful QoL improvements.

To support its claim of improved recovery time, the applicant referred to a single-center, single-arm, observational, retrospective, cohort study by Bolton et al. (2021) of 58 patients with HF–HD at baseline who switched to THERANOVA. The applicant stated that a dialysis unit performed regular assessments of patient-reported symptom burden, using the POS–S Renal Symptom questionnaire and the ''Recovery time from last dialysis session'' question as part of routine patient focused care. The applicant noted that of the 90 people who initially agreed to provide patient reported outcome measures (PROMs) data, the number of participants providing data at 3, 6, 9, and 12 months were 80, 72, 68, and 59 respectively. The applicant concluded that a sustained clinically relevant reduction in post-dialysis recovery time was observed following the therapy switch. The applicant stated that the study results demonstrated that the percentage of patients reporting a recovery time greater than 360 minutes decreased from 36 percent at baseline to 26 percent, 14 percent, 14 percent, and 9 percent at 3, 6, 9, and 12 months, respectively. The applicant noted that additionally, there was a statistically significant improvement in median recovery time from a baseline of 210 minutes (IQR 7.5–600) to 60 minutes after 6 months (0–210; p = 0.002), 60 minutes after 9 months (0–225; p < 0.001), and 105 minutes after 12 months (0–180; p = 0.001).[103]

With respect to the claim that THERANOVA is associated with improved QoL, as indicated by reduced pruritus, improvement in two KDQoL survey domains, and improved London Evaluation of Illness (LEVIL) scores, the applicant described the background and significance of each indicator. The applicant noted that that pruritus can be uncomfortable and significantly interfere with ESRD patients' daily living activities. The applicant asserted that pruritus that is severe or chronic can prevent ESRD patients from sleeping normally,[104] and that in addition to causing sleep loss, pruritus can also cause anxiety and depression.[105] The applicant also noted that prolonged scratching of itchy skin also leads to skin injury, scarring, and infection.[106]

The applicant also explained that one of the most commonly used tools to assess kidney disease QoL in the U.S. is the KDQoL[107] patient survey, which assesses patients' physical and mental well-being, the burden of kidney disease, treatment-associated symptoms and problems, and the effects of kidney disease on daily life. The applicant noted that the survey assesses a patient's ability to accomplish desired tasks, levels of depression and anxiety, the ability to participate in social activities, and some daily life activities.

The applicant also referenced the LEVIL survey, which measures patient-reported outcomes and evaluates well-being, energy level, sleep quality, bodily pain, appetite, and shortness of breath. Per the applicant, the survey is validated, and scores are correlated with acute hospital admissions, abnormal fluid status, and vascular access events.[108]

To support its claim of improved pruritus and improvement in two KDQoL survey domains, the applicant referred to a prospective, open-label, randomized control trial by Lim, Park, et al. (2020). This study randomized patients to either Theranova 400 or a high-flux dialyzer. Forty-nine HD patients (24 using THERANOVA; 25 using a high-flux dialyzer) completed the study. Per the applicant, QoL was assessed at baseline and after 12 weeks of treatment using the KDQoL Short Form-36, and pruritus was assessed using a questionnaire and visual analog scale. The applicant stated that the study concluded that laboratory markers, including serum albumin, did not differ between the two groups after 12 weeks, though removals of kappa and lambda free light chains were greater for THERANOVA than high-flux dialyzer. The applicant noted that the results showed that the THERANOVA group had lower mean scores for morning pruritus distribution (1.29 ± 0.46 vs. 1.64 ± 0.64, p = 0.034) and frequency of scratching during sleep (0.25 ± 0.53 vs. 1.00 ± 1.47, p = 0.023), compared to the high-flux group. The applicant also stated that in the same study, the THERANOVA group also had statistically significant higher scores (indicating better QoL) in KDQoL domains for physical functioning (75.2 ± 20.8 vs. 59.8 ± 30.1, p = 0.042) and physical role (61.5 ± 37.6 vs. 39.0 ± 39.6, p = 0.047), compared to the high-flux group.[109]

To support its claim of improved QoL scores, the applicant referred to a study by Penny et al. (2021). According to the applicant, this was a single-center interventional pilot study with 28 patients established on maintenance HD. The single-arm study consisted of 2-week observation (baseline at conventional HF–HD) followed by 12 weeks of HDx. The study also had an extension phase; where patients had a 2-week baseline period, followed by 24 weeks of HDx, and then an 8-week washout period in which patients returned to HF–HD to assess the presence of any carryover effect. The applicant stated that health-related quality of life (HRQoL) was assessed

[100] Bossola M, et al. Fatigue is associated with increased risk of mortality in patients on chronic hemodialysis. Nephron 2015; 130:113–118.

[101] Koyama H, Fukuda S, Shoji T, Inaba M, Tsujimoto Y, Tabata T, Okuno S, Yamakawa T, Okada S, Okamura M, Kuratsune H, Fujii H, Hirayama Y, Watanabe Y, Nishizawa Y, Fatigue Is a Predictor for Cardiovascular Outcomes in Patients Undergoing Hemodialysis CJASN Apr 2010, 5 (4) 659–666; DOI: 10.2215/CJN.08151109.

[102] Rayner HC, et al. Recovery time, quality of life, and mortality in hemodialysis patients: The Dialysis Outcomes and Practice Patterns Study (DOPPS). Am J Kidney Dis 2014; 64:86–94.

[103] Bolton S, Gair R, Nilsson LG, Matthews M, Stewart L, McCullagh N. Clinical Assessment of Dialysis Recovery Time and Symptom Burden: Impact of Switching Hemodialysis Therapy Mode. Patient Relat Outcome Meas. 2021;12:315–321 *https://doi.org/10.2147/PROM.S325016.*

[104] Mayo Clinic, Itchy skin (pruritus), available at *https://www.mayoclinic.org/diseases-conditions/itchy-skin/symptoms-causes/syc-20355006.*

[105] Ibid.

[106] Ibid.

[107] RAND Corporation, Kidney Disease Quality of Life Instrument (KDQOL), available at *https://www.rand.org/health-care/surveys_tools/kdqol.html.*

[108] Pittman Z, et al. Collection of daily patient reported outcomes is feasible and demonstrates differential patient experience in chronic kidney disease. Hemodialysis International, 2017; 21:265–273.

[109] Lim JH, Park Y, Yook JM, et al. Randomized controlled trial of medium cut-off versus high-flux dialyzers on quality of life outcomes in maintenance hemodialysis patients. Sci Rep. 2020;10(1):7780. Published 2020 May 8. doi:10.1038/s41598–020–64622-z.

using the dynamic PROM instrument, LEVIL, twice weekly. The applicant noted that 22 patients completed all study procedures to contribute to the full 12-week analysis. The applicant asserted that the study results demonstrated that 73 percent of participants who had low overall health-related QoL at baseline with HF–HD (mean, 51.5 ± 10.2; range, 36.1–69.3) had a statistically significant improvement at 8 weeks after switching to HDx (mean, 64.6 ± 16.2; p=0.001) and at 12 weeks (67.2 ± 16.9; p=0.001). The applicant stated that the study also found that all participants had a statistically significant improvement in 'feeling washed out/drained' from baseline with HF–HD (mean, 40.3 ± 20.5; range, 8.7–67.4) to HDx at 8 weeks (59.9 ± 22.8; p=0.001) and at 12 weeks (64.7 ± 19.6; p < 0.001). The applicant noted that likewise, 73 percent of study participants assessed on their 'feeling of general well-being' had a statistically significant improvement from baseline with HF–HD (mean, 43 ± 14.1; range, 19.7–69.5) to HDx at 8 weeks (65.2 ± 21.9; p < 0.001) and at 12 weeks (66.3 ± 17.7; p=0.002). Additionally, the applicant stated that 73 percent of study participants who experienced poor 'sleep quality' had a statistically significant improvement from baseline with HF–HD (37.2 ± 20.1; range, 7.2–66.2) after 4 weeks with HDx (mean, 52.8 ± 26.7; p=0.01), and continually improved at 8 weeks (57 ± 22.2; p=0.002) and 12 weeks (61.7 ± 24.5; p <0.001).[110]

With respect to the claim that THERANOVA is associated with reducing restless leg syndrome (RLS) by 10 percent or more, the applicant stated that RLS is another common and debilitating side effect of long-term dialysis. The applicant noted that an estimated 6.6 percent to 62 percent of patients on long-term dialysis therapy suffer from RLS,[111] with one study suggesting 20 to 25 percent of ESRD patients demonstrated overt (moderate to severe) RLS.[112] The applicant asserted that extreme discomfort of RLS worsens during periods of physical inactivity and at night,[113] contributing to sleep loss and sleep deprivation in ESRD patients, and that loss of sleep carries over into the day for many patients, leaving them feeling lethargic and preventing them from fully engaging in daily activities. The applicant also noted that a study found that RLS among HD patients is associated with a significant increase in new cardiovascular events, that these events increased with the severity of RLS, and that HD patients with RLS had a higher risk of mortality than their non-RLS peers.[114] The applicant also described an additional study that found RLS was associated with significantly higher risk of developing cardiovascular events, strokes, and all-cause mortality among ESRD patients.[115] The applicant explained that RLS is treated with many medications such as dopamine antagonists, benzodiazepines, anti-epileptics, iron dextran, Vitamin C, and intradialytic aerobic exercise—all of which produce side effects and only provide limited improvement in RLS symptoms.[116] The applicant stated that medical interventions for RLS in dialysis populations have not been particularly effective, are costly, and may contribute to polypharmacy and adverse drug reactions in a population already at risk.[117]

To support its claim that THERANOVA is associated with reducing RLS, the applicant referred to a multi-center, observational prospective cohort study by Alarcon et al. (2021) which assessed 992 individuals with HF–HD at baseline, who switched to THERANOVA and were observed over a 12-month period. The applicant explained that changes in KDQoL 36-Item Short Form Survey domains, Dialysis Symptom Index (DSI), and RLS 12 months after switching to THERANOVA were compared with the patient baseline responses on high-flux dialyzers. Per the applicant, the study found a significant decrease in the proportion of patients diagnosed with RLS from 22.1 percent at baseline to 12.5 percent at 6 months, and 10 percent at 12 months (p < 0.0001). Additionally, the applicant stated that a post hoc comparison showed statistically significant differences between each pair of repeated observations (baseline vs. 6 months: p <0.0001; baseline vs. 12 months: p <0.0001; 6 vs. 12 months: p=0.003).[118]

With respect to the claim that THERANOVA reduces the rate of subsequent therapeutic interventions, such as the use of ESAs, iron, and insulin, the applicant stated that almost all dialysis patients and those with CKD experience anemia as a side effect of their treatment, which contributes negative clinical outcomes such as weakness, irregular heartbeat, shortness of breath, dizziness and lightheadedness, chest pain, and headaches.[119] The applicant stated that anemia significantly impairs QoL for dialysis patients and requires additional treatment, and that ESAs are a widely used treatment that mitigates anemia by enabling the body to produce more red blood cells. The applicant asserted that reductions in ESA treatment can preserve or enhance patient QoL and can generate savings to the Medicare program.

With regard to iron supplementation, the applicant noted that iron supplements are another important treatment for patients with renal failure and anemia. The applicant explained that iron deficiency occurs more frequently among patients with ESRD because of an increase in external losses of iron, a decreased ability to store iron in the body, and potential deficits in intestinal iron absorption.[120] The applicant asserted that reductions in iron treatment can preserve or enhance patient QoL and can generate savings to the Medicare program.[121]

Finally, with regard to insulin use, the applicant stated that diabetes is a common comorbidity in ESRD

[110] Penny J., Jarosz P., Salerno F., Lemoine S., McIntyre CW. Impact of Expanded Hemodialysis Using Medium Cut-off Dialyzer on Quality of Life: Application of Dynamic Patient-Reported Outcome Measurement Tool. Kidney Medicine. Published 2021, Jul. 29. *https://doi.org/10.1016/j.xkme.2021.05.010*.

[111] Kavanagh D., et al. Restless legs syndrome in patients on dialysis Am J. Kidney Dis. 2004 May;43(5):763–71.

[112] Winkelman J.W., Chertow G.M., Lazarus J.M.. Restless legs syndrome in end-stage renal disease. Am J. Kidney

[113] Kavanagh D., et al. Restless legs syndrome in patients on dialysis Am J. Kidney Dis. 2004 May;43(5):763–71.

[114] La Manna G., et al. Restless legs syndrome enhances cardiovascular risk and mortality in patients with end-stage kidney disease undergoing long-term haemodialysis treatment. Nephrol Dial Transplant.2011;26(6):1976–83.

[115] Lin C.H., et al. Restless legs syndrome is associated with cardio/cerebrovascular events and mortality in end-stage renal disease. Eur J. Neurol. 2015;22(1):142–9.

[116] Gopaluni S., Sherif M., Ahmadouk N.A. Interventions for chronic kidney disease-associated restless legs syndrome. Cochrane Database Syst Rev 2016; 11: CD010690.

[117] Gopaluni S., Sherif M., Ahmadouk N.A. Interventions for chronic kidney disease-associated restless legs syndrome. Cochrane Database Syst Rev 2016; 11: CD010690.

[118] Alarcon J.C., Bunch A., Ardila F., et al. Impact of Medium Cut-Off Dialyzers on Patient-Reported Outcomes: COREXH Registry. Blood Purification. 2021; 50(1):110–118. DOI: 10.1159/000508803. PMID: 33176299.

[119] Mayo Clinic's overview of anemia, available at *https://www.mayoclinic.org/diseases-conditions/anemia/symptoms-causes/syc-20351360*.

[120] Fishbane S., Maesaka J.K., Iron management in end-stage renal disease, American Journal of Kidney Diseases, Volume 29, Issue 3, 1997, Pages 319–333, ISSN 0272–6386, Accessed at: *https://doi.org/10.1016/S0272-6386(97)90192-X*.

[121] Estimated cost to Medicare based on The Moran Company, an HMA Company analysis calculated using 2020 ESRD claims with IV iron valued at ASP+6%.

patients,[122] and many ESRD patients require additional insulin administration. The applicant asserted that through reductions in insulin use, Medicare could realize cost savings of $3,949 annually per diabetes patient.[123]

To support its claim of reduced rate of subsequent therapeutic interventions such as reduced need for and use of ESAs, iron, and insulin, the applicant referred to three sources. The first source, Lim, Jeon, et al. (2020), was a secondary analysis of a prospective, open-label, randomized controlled trial by Lim, Park, et al. (2020).[124] Lim, Park, et al. (2020) was previously described. According to the applicant, the primary outcome of the secondary analysis was the change in erythropoietin resistance index (ERI; U/kg/wk/g/dL) between baseline and 12 weeks. The applicant stated that the study found statistically significant decreases in ESA dose, weight-adjusted ESA dose, and erythropoiesis resistance index for THERANOVA patients, compared to the high-flux dialyzer group at 12 weeks ($p < 0.05$). The applicant also stated that there was a statistically significant higher serum iron level in the THERANOVA group at 12 weeks (iron [7g/dL]: 72.1 ± 25.4 vs. 55.9 ± 25.0), ($p=0.029$), indicating an improvement in iron metabolism as a potential clinical marker for the reduced need of iron supplementation.[125]

The applicant also referred to the Sanabria et al. (2021) study, previously described, of 81 patients (Year 1, HF–HD; Year 2, HDx with THERANOVA). The applicant stated the study concluded that there was a statistically significant reduction in the mean dose of ESA after switching from HF–HD to HDx with THERANOVA ($p=0.0361$).[126] The applicant also stated that the study found a statistically significant reduction in the mean dose of intravenous iron from 73.46 mg/month with HF–HD to 66.36 mg/month with HDx with THERANOVA ($p=0.003$).[127]

Finally, the applicant referred to the Ariza et al. (2021) study, described previously in this section of the proposed rule. The applicant stated that study authors found a statistically significant reduction in the dosage per patient per year of ESA in international units from 181,318 with HF–HD (95 percent CI: 151,647– 210,988) to 168,124 with HDx with THERANOVA (95 percent CI: 138,452–197,794; $p <0.01$) as well as a statistically significant reduction in dosage per patient per year of iron in milligrams from 959 with HF–HD (95% CI: 760–1158) to 759 with HDx (95 percent CI: 560–958; $p <0.01$).[128] The applicant also asserted that the study found a statistically significant reduction in dosage per patient per year of insulin in international units from 5383 with HF–HD (95 percent CI: 3274–7490) to 3434 with HDx with THERANOVA (95 percent CI: 1327–5543; $p <0.01$).[129]

The applicant also referred to CMS' final determination and public comments regarding its CY 2021 TPNIES application, as summarized in the CY 2021 ESRD PPS final rule (85 FR 71453 through 71458). The applicant stated that stakeholders largely provided favorable comments and supported TPNIES approval for THERANOVA. The applicant noted that in particular, physicians who used THERANOVA and had direct patient experience with the product strongly supported the application.[130] The applicant also noted that some stakeholders, however, expressed concerns about THERANOVA's CY 2021 TPNIES application. Specifically, the applicant stated that commenters noted that the supporting studies had small sample sizes that did not represent the U.S. patient population, and that the duration of the studies was too short. The applicant also stated that some stakeholders expressed a belief that HDx with THERANOVA may result in decreased albumin levels, potentially causing harm to patients. The applicant asserted that with the updated and additional information provided in its CY 2023 application, the applicant has addressed these concerns.

The applicant asserted that all substantial clinical improvement claims included in its CY 2023 application are now supported by at least one study that has undergone full peer review and has been published, or accepted for publication and is being prepared for publishing. The applicant explained that the application's supporting studies feature statistically significant findings and have a range of appropriate sample sizes, such as Molano-Triviño et al., n=1,098,[131] and Alarcon et al., n=992,[132] previously described. The applicant explained that additionally, many studies evaluated THERANOVA's impacts over an extended period, including year-long evaluations after patients transitioned from conventional therapy to HDx therapy, for example, Sanabria et al.[133] and Ariza et al.,[134] previously described. The applicant stated that it considers the studies supporting the application and their findings to be applicable and generalizable to the U.S. Medicare population, and that this generalizability is bolstered by the additional U.S.-specific information and findings. The applicant asserted that while it does not believe that results in sample populations would significantly differ from results in the U.S. patient population, the application also now includes additional evidence that

[122] Approximately one in three adults with diabetes also have CKD. See CDC, Diabetes and Chronic Kidney Disease, *https://www.cdc.gov/diabetes/managing/diabetes-kidney-disease.html.*

[123] Average cost per patient for insulin taken from KFF report on Part D spending, available at *https://www.kff.org/medicare/issue-brief/how-much-does-medicare-spend-on-insulin/.*

[124] Lim J.H., Park Y., Yook J.M., et al. Randomized controlled trial of medium cut-off versus high-flux dialyzers on quality of life outcomes in maintenance hemodialysis patients. Sci Rep. 2020;10(1):7780. Published 2020 May 8. doi:10.1038/s41598–020–64622–z.

[125] Lim J.H., Jeon Y., Yook J.M., et al. Medium cut-off dialyzer improves erythropoiesis stimulating agent resistance in a hepcidin-independent manner in maintenance hemodialysis patients: results from a randomized controlled trial. Sci Rep. 2020;10(1):16062. Published 2020 Sep 29. doi:10.1038/s41598–020–73124–x.

[126] Sanabria R.M., Hutchison C.A., Vesga J.I., Ariza J.G., Sanchez R., Suarez A.M. Expanded Hemodialysis and Its Effects on Hospitalizations and Medication Usage: A Cohort Study. Nephron 2021;145:179–187. doi: 10.1159/000513328.

[127] Ibid.

[128] Ariza, J.G., Walton, S.M., Suarez, A.M., Sanabria, M., Vesga, J.I. An initial evaluation of expanded hemodialysis on hospitalizations, drug utilization, costs, and patient utility in Colombia. Ther Apher Dial. 2021; 25: 621– 627. *https://doi.org/10.1111/1744-9987.13620.*

[129] Ibid.

[130] See for example, Dr. Peter Stenvinkel (Karolinska University Hospital) at *https://beta.regulations.gov/comment/CMS-2020-0079-0038;* Dr. Vincenzo Cantaluppi (Novara University Hospital) at *https://beta.regulations.gov/comment/CMS-2020-0079-0066;* Dr. Colin Hutchison (Central Hawkes Bay Health Centre) at *https://beta.regulations.gov/comment/CMS-2020-0079-0065;* Dr. Andrew Davenport (Royal Free Hospital) at *https://beta.regulations.gov/comment/CMS-2020-0079-0037;* Dr. Mario Cozzolino (University of Milan) at *https://beta.regulations.gov/comment/CMS-2020-0079-0062;* Dr. Jang-Hee Cho (Kyungpook National University Hospital) at *https://beta.regulations.gov/comment/CMS-2020-0079-0061.*

[131] Molano A.P., Hutchison C.A., Sanchez R., Rivera A.S., Buitrago G., Dazzarola M.P., Munevar M., Guerrero M., Vesga J.I., Sanabria M., Medium Cut-Off Versus High-Flux Hemodialysis Membranes and Clinical Outcomes: A Cohort Study Using Inverse Probability Treatment Weighting, Kidney Medicine (2022), doi: *https://doi.org/10.1016/j.xkme.2022.100431.*

[132] Alarcon J.C., Bunch A., Ardila F., et al. Impact of Medium Cut-Off Dialyzers on Patient-Reported Outcomes: COREXH Registry. Blood Purification. 2021; 50(1):110–118. DOI: 10.1159/000508803. PMID: 33176299.

[133] Sanabria R.M., Hutchison C.A., Vesga J.I., Ariza J.G., Sanchez R., Suarez A.M. Expanded Hemodialysis and Its Effects on Hospitalizations and Medication Usage: A Cohort Study. Nephron 2021;145:179–187. doi: 10.1159/000513328

[134] Ariza, J.G., Walton, S.M., Suarez, A.M., Sanabria, M., Vesga, J.I. An initial evaluation of expanded hemodialysis on hospitalizations, drug utilization, costs, and patient utility in Colombia. Ther Apher Dial. 2021; 25: 621– 627. *https://doi.org/10.1111/1744-9987.13620.*

directly addressed U.S. patients, including: a new study on U.S. hospitalization rates; new survey data from U.S. patients, health care providers, and payers, which demonstrated THERANOVA's value, clinical improvements, and QoL enhancements; [135] and includes new testimonials in support of the TPNIES application for THERANOVA from U.S. kidney care providers: a nephrologist with 10 years of experience, dialysis nurse with 15 years of experience, and a pediatric dialysis nurse practitioner with over 10 years of experience. The applicant noted that the survey data came from three separate double-blinded surveys presented to each respondent group with information about THERANOVA's benefits and then assessed reactions—including patients' interest in switching from their current HD therapy to THERANOVA's HDx therapy, the likelihood that health care providers would recommend THERANOVA to patients and colleagues, and payers' evaluations of THERANOVA's potential to generate value for their health plans and patient enrollees. The applicant noted that overall, patients overwhelmingly wanted to use THERANOVA, health care providers strongly indicated that they would recommend THERANOVA to patients and peers, and payers identified several of THERANOVA's improvements as generating value. The applicant asserted that the peer-validated studies, and additional evidence that further addresses the U.S. patient population, provide the support necessary to conclude that THERANOVA is a substantial clinical improvement over existing technologies.

The applicant also stated that in addition to THERANOVA's demonstrated effectiveness, additional evidence demonstrates THERANOVA's safety. The applicant explained that in the time since it submitted the CY 2021 TPNIES application to CMS, FDA reviewed THERANOVA's randomized, controlled clinical IDE trial and additional evidence supporting THERANOVA's safety and effectiveness, and granted marketing authorization. The applicant stated that the IDE trial demonstrated that THERANOVA's HDx therapy provides superior removal of harmful LMMs while maintaining adequate serum albumin levels.[136] The applicant noted that FDA's comprehensive review and subsequent approval of THERANOVA establishes THERANOVA's safety and effectiveness for its intended use: treatment of chronic kidney failure.

(b) CMS Preliminary Assessment of Substantial Clinical Improvement Claims and Sources

After a review of the information provided by the applicant, we note that the applicant submitted the full, published peer-reviewed papers for several of the abstracts, posters, and incomplete manuscripts that were previously submitted with its CY 2021 TPNIES application,[137] [138] [139] [140] [141] [142] and the remaining evidence submitted with the CY 2023 application was new. We have identified the following concerns regarding THERANOVA and the substantial clinical improvement eligibility criteria for the TPNIES. We note that, consistent with § 413.236(c), CMS will announce its final determination regarding whether THERANOVA meets the substantial clinical improvement criteria and other eligibility criteria for the TPNIES in the CY 2023 ESRD PPS final rule.

With respect to the applicant's claim that THERANOVA leads to reduced hospitalization rates, we note that the applicant included studies from the previous submission and supplemented with newer studies, such as the Tran et. al. (2021) poster abstract. We note that the poster abstract was a post hoc analysis of a previous open-label study,[143] which had an average follow-up period of 4.5 months in the THERANOVA group. We question whether this short time period is sufficient to see changes in hospitalization from interventions aimed at increasing clearance of uremic toxins. It may be helpful to see if this outcome is sustained in longer term follow-up.[144]

We also note that, although authors in the Molano et. al. (2022) study used inverse probability treatment weighting (IPTW), the study was unblinded and could influence treatment decisions in the group using the THERANOVA dialyzer. Moreover, we note that patients seemed healthier in the THERANOVA arm, and had more fistulas, fewer catheters, and higher Karnofsky indices. We also note that the THERANOVA arm had more intensive dialysis at baseline and throughout the duration of the study (Kt/V of 1.7 vs. 1.6), suggestive of more intensive small molecule clearance and more intensive dialysis overall. Therefore, it is unclear whether the outcome differences between the two arms could be due to factors other than the dialyzer type. We question whether IPTW would be sufficient to overcome these biases, especially the Kt/V bias, which persisted even after the baseline period.[145]

In addition, we note that the studies by Ariza et al. (2021) [146] and Sanabria et al. (2021),[147] using the same study sample population, were limited by absence of a control group, and had non-significant differences in hospitalization rate between baseline HF–HD and after switching to HDx: 0.77

[135] Patient Preference for a Future Dialyzer Study, prepared by Beghou Consulting on behalf of Baxter International. Survey results; December 2021.

[136] Weiner D., et al. Efficacy and Safety of Expanded Hemodialysis with the Theranova 400 Dialyzer: A Randomized Controlled Trial, CJASN15: 1310–1319, 2020. doi: 10.2215/CJN.01210120.

[137] Alarcon J.C., Bunch A., Ardila F., et al. Impact of Medium Cut-Off Dialyzers on Patient-Reported Outcomes: COREXH Registry. Blood Purification. 2021; 50(1):110–118. DOI: 10.1159/000508803. PMID: 33176299.

[138] Ariza, J.G., Walton, S.M., Suarez, A.M., Sanabria, M., Vesga, J.I. An initial evaluation of expanded hemodialysis on hospitalizations, drug utilization, costs, and patient utility in Colombia. Ther Apher Dial. 2021; 25: 621– 627. *https://doi.org/10.1111/1744-9987.13620.*

[139] Bolton S., Gair R., Nilsson L.G., Matthews M., Stewart L., McCullagh N. Clinical Assessment of Dialysis Recovery Time and Symptom Burden: Impact of Switching Hemodialysis Therapy Mode. Patient Relat Outcome Meas.2021;12:315–321 *https://doi.org/10.2147/PROM.S325016.*

[140] Lim J.H., Jeon Y., Yook J.M., et al. Medium cut-off dialyzer improves erythropoiesis stimulating agent resistance in a hepcidin-independent manner in maintenance hemodialysis patients: results from a randomized controlled trial. Sci Rep. 2020;10(1):16062. Published 2020 Sep 29. doi:10.1038/s41598–020–73124–x.

[141] Lim J.H., Park Y., Yook J.M., et al. Randomized controlled trial of medium cut-off versus high-flux dialyzers on quality of life outcomes in maintenance hemodialysis patients. Nature Sci Rep. 2020;10(1):7780. Published 2020 May 8. doi:10.1038/s41598–020–64622–z.

[142] Sanabria R.M., Hutchison C.A., Vesga J.I., Ariza J.G., Sanchez R., Suarez A.M. Expanded Hemodialysis and Its Effects on Hospitalizations and Medication Usage: A Cohort Study. Nephron 2021;145:179–187. doi: 10.1159/000513328.

[143] Weiner D., et al. Efficacy and Safety of Expanded Hemodialysis with the Theranova 400 Dialyzer: A Randomized Controlled Trial, CJASN15: 1310–1319, 2020. doi: 10.2215/CJN.01210120.

[144] Tran H., Falzon L., Bernardo A., Beck W., Blackowicz M. Reduction in all-cause Hospitalization Events Seen in a Randomized Controlled Trial Comparing Expanded Hemodialysis vs High-Flux Dialysis. Annual Dialysis Conference. Abstract #1070. Published 2021 Jan 28.

[145] Molano A.P., Hutchison C.A., Sanchez R., Rivera A.S., Buitrago G., Dazzarola M.P., Munevar M., Guerrero M., Vesga J.I., Sanabria M., Medium Cut-Off Versus High-Flux Hemodialysis Membranes and Clinical Outcomes: A Cohort Study Using Inverse Probability Treatment Weighting, Kidney Medicine (2022), doi: *https://doi.org/10.1016/j.xkme.2022.100431.*

[146] Ariza, JG, Walton, SM, Suarez, AM, Sanabria, M, Vesga, JI. An initial evaluation of expanded hemodialysis on hospitalizations, drug utilization, costs, and patient utility in Colombia. Ther Apher Dial. 2021; 25: 621– 627. *https://doi.org/10.1111/1744-9987.13620.*

[147] Sanabria RM, Hutchison CA, Vesga JI, Ariza JG, Sanchez R., Suarez AM. Expanded Hemodialysis and Its Effects on Hospitalizations and Medication Usage: A Cohort Study. Nephron 2021;145:179–187. doi: 10.1159/000513328.

(95 percent CI: 0.60–0.98, 61 events) to 0.71 (95 percent CI: 0.55–0.92, 57 events), p=0.6987.

With respect to the applicant's claim that THERANOVA leads to improved QoL, we note that in the study by Lim, Park, et al. (2020), it is unclear if these findings could result from chance alone, when considering the many QoL outcomes examined, due to multiple-hypothesis testing concerns. In particular, we note that differences associated with use of THERANOVA were statistically significant in only 2 out of 26 QoL outcomes assessed, and in both cases the p-value was greater than 0.04. We also note that although the THERANOVA group had lower mean scores for morning pruritus distribution (p=0.034), there was a non-significant difference in afternoon pruritis distribution between the two groups (p=0.347).[148]

Overall, we note that most of studies in the updated evidence submitted for the CY 2023 application are open-label and observational, which may potentially bias results. We also note that many of the studies are single-arm studies that do not employ a control group, which may make it difficult to determine if observed improvements in clinical outcomes are due to the use of THERANOVA or if the improvements may have also occurred with previously available dialysis membranes.[149] [150] [151] [152]

We are inviting public comment as to whether THERANOVA meets the TPNIES substantial clinical improvement criteria.

(6) Capital-Related Assets Criterion (§ 413.236(b)(6))

With respect to the sixth TPNIES eligibility criterion under § 413.236(b)(6), limiting capital-related assets from being eligible for the TPNIES, except those that are home dialysis machines, the applicant did not address this criterion within its application. However, THERANOVA does not meet the definition of a capital-related asset, as defined in § 413.236(a)(2), because it is not an asset that the ESRD facility has an economic interest in through ownership and is subject to depreciation.[153] We welcome comments on THERANOVA's status as a non-capital related asset.

d. Continuation of Approved Transitional Add-On Payment Adjustments for New and Innovative Equipment and Supplies for CY 2023

In this section of the proposed rule, we provide a table that identifies the one item that was approved for the TPNIES for CY 2022 [154] and which is still in the TPNIES payment period, as specified in § 413.236(d)(1), for CY 2023. CMS will continue paying for this item using the TPNIES for CY 2023. This table also identifies the item's HCPCS coding information as well as the payment adjustment effective date and end date.

TABLE 14: Continuation of Approved Transitional Add-On Payment Adjustments for New and Innovative Equipment and Supplies

HCPCS Code	Long Descriptor	Payment Adjustment Effective Date	Payment Adjustment End Date
E1629	Tablo hemodialysis system for the billable dialysis service	1/1/2022	12/31/2023

e. Continuation of Approved Transitional Drug Add-On Payment Adjustments for New Renal Dialysis Drugs or Biological Products for CY 2023

Under § 413.234(c)(1), a new renal dialysis drug or biological product that is considered included in the ESRD PPS base rate is paid the TDAPA for 2 years. In December 2021, CMS approved *Korsuva*™ (difelikafalin) for the TDAPA under the ESRD PPS, effective April 1, 2022. Implementation instructions are specified in CMS Transmittal 11295,[155] dated March 15, 2022, and available at: *https://www.cms.gov/files/document/r11295CP.pdf*.

In this section of the proposed rule, we provide a table that identifies the one new renal dialysis drug that was approved for the TDAPA effective in CY 2022, and for which the TDAPA payment period as specified in § 413.234(c)(1) will continue in CY 2023. This table also identifies the product's HCPCS coding information as well as the payment adjustment effective date and end date.

[148] Lim JH, Park Y., Yook JM, et al. Randomized controlled trial of medium cut-off versus high-flux dialyzers on quality of life outcomes in maintenance hemodialysis patients. Nature Sci Rep. 2020;10(1):7780. Published 2020 May 8. doi:10.1038/s41598–020–64622–z.

[149] Bolton S., Gair R., Nilsson LG, Matthews M., Stewart L., McCullagh N. Clinical Assessment of Dialysis Recovery Time and Symptom Burden: Impact of Switching Hemodialysis Therapy Mode. Patient Relat Outcome Meas.2021;12:315–321 *https://doi.org/10.2147/PROM.S325016*.

[150] Penny J., Jarosz P., Salerno F., Lemoine S., McIntyre CW. Impact of Expanded Hemodialysis Using Medium Cut-off Dialyzer on Quality of Life: Application of Dynamic Patient-Reported Outcome Measurement Tool. Kidney Medicine. Published 2021, Jul. 29. *https://doi.org/10.1016/j.xkme.2021.05.010*.

[151] Alarcon JC, Bunch A., Ardila F., et al. Impact of Medium Cut-Off Dialyzers on Patient-Reported Outcomes: COREXH Registry. Blood Purification. 2021; 50(1):110–118. DOI: 10.1159/000508803. PMID: 33176299.

[152] Lim JH, Jeon Y., Yook JM, et al. Medium cut-off dialyzer improves erythropoiesis stimulating agent resistance in a hepcidin-independent manner in maintenance hemodialysis patients: results from a randomized controlled trial. Sci Rep. 2020;10(1):16062. Published 2020 Sep 29. doi:10.1038/s41598–020–73124–x.

[153] See also: CMS Provider Reimbursement Manual, Chapter 1, Section 104.1. Available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929*.

[154] 86 FR 61889 through 61906.

[155] CMS Transmittal 11295 rescinded and replaced CMS Transmittal 11278, dated February 24, 2022.

TABLE 15: Continuation of Approved Transitional Drug Add-On Payment Adjustments for New Renal Dialysis Drugs or Biological Products

HCPCS Code	Long Descriptor	Payment Adjustment Effective Date	Payment Adjustment End Date
J0879	Injection, difelikefalin, 0.1 microgram, (for esrd on dialysis)	4/1/2022	3/31/2024

D. Request for Information About Addressing Issues of Payment for New Renal Dialysis Drugs and Biological Products After Transitional Drug Add-On Payment Adjustment (TDAPA) Period Ends

1. Background on the TDAPA

Section 217(c) of PAMA required the Secretary to establish a process for including new injectable and intravenous (IV) products into the ESRD PPS bundled payment as part of the CY 2016 ESRD PPS rulemaking. Therefore, in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027), we finalized a process based on our longstanding drug designation process that allowed us to include new injectable and intravenous products into the ESRD PPS bundled payment and, when appropriate, modify the ESRD PPS payment amount. We codified this process in our regulations at 42 CFR 413.234. We finalized that the process is dependent upon the ESRD PPS functional categories, consistent with the drug designation process we have followed since the implementation of the ESRD PPS in 2011. As we explained in the CY 2016 ESRD PPS final rule (80 FR 69014), when we implemented the ESRD PPS, drugs and biological products were grouped into functional categories based on their action. This was done for the purpose of adding new drugs or biological products with the same functions to the ESRD PPS bundled payment as expeditiously as possible after the drugs are commercially available so beneficiaries have access to them. As we stated in the CY 2011 ESRD PPS final rule, we did not specify all of the drugs and biological products within these categories because we did not want to inadvertently exclude drugs that may be substitutes for drugs we identified and we wanted the ability to reflect new drugs and biological products developed or changes in standards of practice (75 FR 49052).

In the CY 2016 ESRD PPS final rule, we finalized the definition of an ESRD PPS functional category in § 413.234(a) as a distinct grouping of drugs or biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD (80 FR 69077).

We finalized a policy in the CY 2016 ESRD PPS final rule that if a new renal dialysis injectable or IV product falls within an existing functional category, the new injectable drug or IV product is considered included in the ESRD PPS bundled payment and no separate payment is available. The new injectable or IV product qualifies as an outlier service. We noted in that rule that the ESRD bundled market basket updates the ESRD PPS base rate annually and accounts for price changes of the drugs and biological products.

We also finalized in the CY 2016 ESRD PPS final rule that, if the new renal dialysis injectable or IV product does not fall within an existing functional category, the new injectable or IV product is not considered included in the ESRD PPS bundled payment and the following steps occur. First, an existing ESRD PPS functional category is revised or a new ESRD PPS functional category is added for the condition that the new injectable or IV product is used to treat or manage. Next, the new injectable or IV product is paid for using the TDAPA codified in § 413.234(c). Finally, the new injectable or IV product is added to the ESRD PPS bundled payment following payment of the TDAPA.

In the CY 2016 ESRD PPS final rule, we finalized a policy in § 413.234(c) to pay the TDAPA until sufficient claims data for rate setting analysis for the new injectable or IV product are available, but not for less than 2 years. The new injectable or IV product is not eligible as an outlier service during the TDAPA period. We established that following the TDAPA period, the ESRD PPS base rate will be modified, if appropriate, to account for the new injectable or IV product in the ESRD PPS bundled payment.

In CYs 2019 and 2020 ESRD PPS final rules (83 FR 56927 through 56949 and 84 FR 60653 through 60677, respectively), we made several revisions to the drug designation process regulations at § 413.234. In the CY 2019 ESRD PPS final rule, we revised regulations at § 413.234(a), (b), and (c) to reflect that the process applies for all new renal dialysis drugs and biological products that are FDA approved regardless of the form or route of administration. In addition, we revised § 413.234(b) and (c) to expand the TDAPA to all new renal dialysis drugs and biological products, rather than just those in new ESRD PPS functional categories. In the CY 2020 ESRD PPS final rule, we revised § 413.234(b) and added paragraph (e) to exclude from TDAPA eligibility generic drugs approved by FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act and drugs for which the new drug application is classified by the FDA as Type 3, 5, 7 or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the ''parent NDA'' is a Type 3, 5, 7, or 8, effective January 1, 2020.

Under our current TDAPA policy at § 413.234(c), a new renal dialysis drug or biological product that falls within an existing ESRD PPS functional category is considered included in the ESRD PPS base rate and is paid the TDAPA for 2 years. After the TDAPA period, the base rate will not be modified. If the new renal dialysis drug or biological product does not fall within an existing ESRD PPS functional category, it is not considered included in the ESRD PPS base rate, and it will be paid the TDAPA until sufficient claims data for rate setting analysis is available, but not for less than 2 years. After the TDAPA period, the ESRD PPS base rate will be modified, if appropriate, to account for the new renal dialysis drug or biological

product in the ESRD PPS bundled payment.

As discussed in the CY 2019 and CY 2020 ESRD PPS final rules, for new renal dialysis drugs and biological products that fall into an existing ESRD PPS functional category, the TDAPA helps ESRD facilities to incorporate new drugs and biological products and make appropriate changes in their businesses to adopt such products, provides additional payments for such associated costs, and promotes competition among the products within the ESRD PPS functional categories, while focusing Medicare resources on products that are innovative (83 FR 56935; 84 FR 60654). For new renal dialysis drugs and biological products that do not fall within an existing ESRD PPS functional category, the TDAPA is a pathway toward a potential base rate modification (83 FR 56935).

For the complete history of the TDAPA policy, including the pricing methodology, please see the CY 2016 ESRD PPS final rule (80 FR 69023 through 69024), CY 2019 ESRD PPS final rule (83 FR 56932 through 56948), and CY 2020 ESRD PPS final rule (84 FR 60653 through 60681).

2. Current Issues and Concerns of Interested Parties

In the CY 2019 ESRD PPS final rule, we discussed that a commenter stated concern over beneficiary access issues at the end of the TDAPA period. We responded by noting the drug or biological product will become eligible under the outlier policy after the TDAPA period if it is not considered to be a composite rate drug. We stated that we expect that if a beneficiary is responding well to a drug or biological product paid for using the TDAPA that they will continue to have access to that therapy after the TDAPA period ends (83 FR 56941). Since 2019, dialysis associations and pharmaceutical representatives have expressed concerns to CMS about payment following the TDAPA period for new renal dialysis drugs and biological products that are paid for using the TDAPA. They asserted that unless money is added to the ESRD PPS base rate for these drugs and biological products, similar to what occurred with calcimimetics (85 FR 71406 through 71410), then it is unlikely that ESRD facilities would be able to sustain the expense of these drugs and biological products when the TDAPA period ends. Further, they cautioned that uncertainty about payment could affect ESRD facility adoption of these drugs and biological products during the TDAPA period. To date, calcimimetics are the only renal dialysis drugs or biological products that have been paid for using the TDAPA and incorporated into the ESRD PPS bundled payment following the TDAPA payment period. There have been no other renal dialysis drugs or biological products that have completed their TDAPA payment period, and as a result CMS does not yet have data on other drugs or biological products in order to evaluate the specific risks and access challenges that interested parties have raised.

As mentioned in the CY 2019 (83 FR 56941) and CY 2020 (84 FR 60672 and 60693) ESRD PPS final rules, many commenters suggested a rate-setting exercise at the end of TDAPA for all new renal dialysis drugs and biological products. We responded by noting that we do not believe adding dollars to the ESRD PPS base rate would be appropriate for new drugs that fall into the ESRD PPS functional categories given that the purpose of the TDAPA for these drugs is to help ESRD facilities incorporate new drugs and biological products and make appropriate changes in their businesses to adopt such products, provide additional payments for such associated costs, and promote competition among the products within the ESRD PPS functional categories. In addition, we explained that the ESRD PPS base rate already includes money for renal dialysis drugs and biological products that fall within an existing ESRD PPS functional category. Under a PPS, Medicare makes payments based on a predetermined, fixed amount that reflects the average patient, and there will be patients whose treatment costs at an ESRD facility would be more or less than the ESRD PPS payment amount. A central objective of the ESRD PPS and of prospective payment systems in general is for facilities to be efficient in their resource use.

We also note that price changes to the ESRD bundled payment are updated annually by the ESRDB market basket, which includes a pharmaceuticals cost category weight, as noted in section II.B.1.a.(1)(b) of this proposed rule. In addition, our analysis of renal dialysis drugs and biological products paid for under the ESRD PPS has found costs and utilization to have decreased over time relative to market basket growth for some high volume formerly separately billable renal dialysis drugs. Therefore, we believe that any potential methodology for an add-on payment adjustment in these circumstances should adapt to changes in price and utilization over time.

3. Suggestions for Possible Methodologies for an Add-On Payment Adjustment for Certain Renal Dialysis Drugs and Biological Products Within an Existing Functional Category

Section 1881(b)(14)(D)(iv) of the Act provides that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate, such as a payment adjustment—(I) for pediatric providers of services and renal dialysis facilities; (II) by a geographic index, such as the index referred to in paragraph (12)(D), as the Secretary determines to be appropriate; and (III) for providers of services or renal dialysis facilities located in rural areas. In response to the patient access concerns discussed previously in this section of the proposed rule, we are considering whether it would be appropriate to establish an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after their TDAPA period ends. We note that any add-on payment adjustment would be subject to the Medicare Part B beneficiary co-insurance payment under ESRD PPS. We are considering a number of methods that could be used to develop an add-on payment adjustment for these drugs and biological products. The methods presented below differ in terms of which formerly separately billable renal dialysis drugs and biological products would be considered for a potential add-on payment adjustment. We note that under these potential options, we would apply a reconciliation methodology only when an add-on payment adjustment would align resource use with payment for a renal dialysis drug or biological product in an existing ESRD PPS functional category.

- Reconcile the average expenditure per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA with any reduction in the expenditure per treatment across all other formerly separately billable renal dialysis drugs and biological products. For example, if the reduction in the cost of all formerly separately billable renal dialysis drugs and biological products per treatment excluding the renal dialysis drug or biological product that was paid for using the TDAPA is $5 and the cost per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA is $10, the add-on payment adjustment per treatment would be $10 minus $5, which is $5. The reductions in formerly separately billable renal dialysis drug and biological products expenditures

per treatment would be calculated by using the difference between these expenditures in the most recent year with claims data available and these expenditures in the current base year for the ESRDB market basket, proposed to be CY 2020 in this rule. For example, if the rule year for which we are calculating the add-on payment adjustment is CY 2023 and the base year for the ESRDB market basket is CY 2020, the reduction in formerly separately billable renal dialysis drugs and biological products expenditures would be the difference between these expenditures in CY 2021 (the year with the most recent claims data) and those in CY 2020.

- Reconcile the average expenditure per treatment for the renal dialysis drug or biological product that was paid for using the TDAPA with any reduction in expenditures for other formerly separately billable renal dialysis drugs or biological products, where such reduction can be empirically attributed to the renal dialysis drug or biological product that was paid for using the TDAPA. For example, if the utilization of the renal dialysis drug or biological product that was paid for using the TDAPA was found to be statistically associated with reduction in expenditure of one drug in an ESRD PPS functional category amounting to $1 per treatment, and the cost per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA is $10, the add-on payment adjustment per treatment would be $10 minus $1, which is $9.
- Reconcile the average expenditure per treatment for the renal dialysis drug or biological product that was paid for using the TDAPA with any reduction in expenditures for other formerly separately billable renal dialysis drugs that fall into one or more ESRD PPS functional categories, where such expenditure reduction is data-driven, based on end action effect, to be attributable to the renal dialysis drug or biological product that was paid for using the TDAPA. Such a data-driven determination would be made by CMS. For example, if the cost per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA is $10 and the reduction in the expenditure for other clinically related formerly separately billable renal dialysis drugs is $0.50 per treatment, the add-on payment adjustment would be $10 minus $0.50, which is $9.50.
- Only use the average expenditure per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA. For example, if the per treatment cost of the renal dialysis drug or biological product that was paid for using the TDAPA is $10, this would be the amount of the add-on payment adjustment.

4. Request for Information on an Add-On Payment Adjustment After the TDAPA Period Ends

We are considering options regarding an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period ends. We are issuing a request for information to seek feedback from the public on the following questions. When responding, please note the question to which your comment is addressing.

- Is an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period ends needed? If so, why? What criteria should CMS establish to determine which renal dialysis drugs or biological products would be included in the calculation for an add-on payment adjustment after the TDAPA period ends?
- If an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period is needed, are the methods discussed in section II.D.4 of this proposed rule sufficient to address the add-on payment adjustment?

++ Which method would be most appropriate?

++ Are there changes to the methodologies that CMS should consider to improve our ability to align payment for renal dialysis services with resource utilization? Please provide as much detail as possible.

++ Are there other methodologies that CMS should consider? Please provide as much detail as possible.

While we will not be responding to specific comments submitted in response to this RFI, we intend to use this input to inform future policy development. Any potential payment policies related to this RFI would be proposed through a separate notice and comment rulemaking. We look forward to receiving feedback on these topics, and note that responses to the RFI should focus on how the suggestions could be applied to the ESRD PPS. Data to support any proposed approaches will be extremely important, so please include any data that supports your comments.

E. Requests for Information on Health Equity Issues Within the ESRD PPS With a Focus on the Pediatric Payment

1. Background

CMS is committed to achieving equity in health care for our beneficiaries by recognizing and working to redress inequities in our policies and programs that serve as barriers to access to care and quality health outcomes. In this proposed rule, ''health equity means the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.'' [156]

Significant and persistent inequities in health care outcomes exist in the United States. Belonging to a racial or ethnic minority group; living with a disability; being a member of the LGBTQ+ community; living in a rural area; or being near or below the Federal Poverty Level, are factors frequently associated with worse health outcomes.[157] [158] [159] [160] [161] [162] [163] [164] Numerous studies have shown that among Medicare beneficiaries, individuals belonging to a racial or ethnic minority group often experience delays in care, receive lower quality of care, report dissatisfactory experiences of care, and experience more frequent hospital readmissions and procedural complications than white patients and

[156] *https://www.cms.gov/pillar/health-equity.*

[157] Joynt KE, Orav E., Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011; 305(7):675–681.

[158] Lindenauer PK, Lagu T., Rothberg MB, et al. Income Inequality and 30-Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. British Medical Journal. 2013; 346.

[159] Trivedi AN, Nsa W., Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014; 371(24):2298–2308.

[160] Polyakova, M., et al. Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. Health Affairs. 2021; 40(2): 307–316.

[161] Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018. Available at: *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf.*

[162] *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[163] *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.*

[164] Poteat TC, Reisner SL, Miller M., Wirtz AL. COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. *medRxiv.* 2020;2020.07.21.20159327. Published 2020 Jul 24. doi:10.1101/2020.07.21.20159327.

patients with a higher levels of income.[165] [166] [167] [168] [169] [170] When compared to FFS beneficiaries not receiving renal dialysis services, FFS beneficiaries receiving renal dialysis services are disproportionately young, male, disabled, Black/African-American, low income as measured by dually eligible Medicare and Medicaid status, and reside in an urban setting.[171]

a. Underserved Communities in the ESRD Medicare Population

During the TEP held in December 2021, CMS's ESRD data contractor provided data stratified by the following factors to TEP participants in order to identify subpopulations for which health disparities may exist among the ESRD population: sex, age, race/ethnicity, urban/rural residence, socioeconomic status proxy (combines both dual eligibility and receipt of premium subsidy for Part D), original reason for Medicare entitlement, and the Area Deprivation Index (ADI) for the beneficiary's residence (which also serves as a proxy for socioeconomic status). Definitions for these categories as well as relevant results, based on enrollment numbers in January 2020, are detailed below.

- Sex [172]—The ESRD PPS population was 58.7 percent male compared to 46.9 percent male in the non-ESRD Medicare population.
- Age [173]—The ESRD PPS population was younger than the non-ESRD Medicare population, in part because ESRD is a qualifying condition for Medicare, regardless of age, if the individual otherwise meets Social Security benefit qualifications.[174] Approximately 40 percent of the ESRD PPS beneficiary population was younger than 60 compared to 10 percent in the non-ESRD Medicare population.
- Original Reason for Medicare Entitlement—The ESRD Medicare population had a higher proportion of beneficiaries entitled to Medicare due to disability compared to the non-ESRD population. Forty-seven percent of the ESRD population was originally eligible for Medicare due to disability (with or without ESRD), compared to 21 percent for the non-ESRD Medicare population.[175]
- Race and Ethnicity [176]—Members of racial or ethnic minority groups comprised a larger proportion of the ESRD Medicare population compared to the non-ESRD Medicare population. This was especially true among Blacks/African-Americans who comprised 34.5 percent of the ESRD population, compared to 8.9 percent of the non-ESRD Medicare population.
- Urban and Rural Residency [177]—ESRD Medicare beneficiaries were more likely to reside in urban areas than the non-ESRD Medicare population. Approximately 84 percent of ESRD beneficiaries lived in urban areas, while approximately 79.6 percent of the non-ESRD Medicare population lived in urban areas.
- Socioeconomic status proxy [178]—42.5 percent of the ESRD Medicare population was dually eligible for Medicare and Medicaid as compared to 15.4 percent of the non-ESRD Medicare population. As compared to the non-ESRD Medicare population, ESRD Medicare beneficiaries were more likely to be enrolled in Medicare Part D (73 percent ESRD PPS as compared to 61 percent of non-ESRD Medicare beneficiaries). Among ESRD Medicare beneficiaries, Non-Hispanic White beneficiaries are less likely to be enrolled in Medicare Part D (70.0 percent Part D enrollment) compared to other groups (ranging from 72.3 to 77.2 percent enrolled in Part D).[179]
- ADI [180]—ESRD Medicare beneficiaries were more likely to be living in socioeconomically disadvantaged neighborhoods compared to non-ESRD Medicare beneficiaries, approximately 29 percent of the ESRD PPS population resided in the most disadvantaged ADI percentiles (76th to 100th percentile) compared to 19.2 percent of non-ESRD Medicare beneficiaries. ESRD beneficiaries who were socioeconomically disadvantaged were more likely to be enrolled in Medicare Part D than those less disadvantaged. Based on the demographics of the Medicare ESRD

[165] Martino, SC, Elliott, MN, Dembosky, JW, Hambarsoomian, K, Burkhart, Q, Klein, DJ, Gildner, J, and Haviland, AM. Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage. Baltimore, MD: CMS Office of Minority Health. 2020.

[166] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[167] Singh JA, Lu X, Rosenthal GE, Ibrahim S., Cram P. Racial disparities in knee and hip total joint arthroplasty: an 18-year analysis of national Medicare data. Ann Rheum Dis. 2014 Dec; 73(12):2107–15.

[168] Rivera-Hernandez M., Rahman M., Mor V., Trivedi AN. Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. J Am Geriatr Soc. 2019 Aug;67(8):1672–1679.

[169] Joynt KE, Orav E., Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[170] Tsai TC, Orav EJ, Joynt KE. Disparities in surgical 30-day readmission rates for Medicare beneficiaries by race and site of care. Ann Surg. Jun 2014;259(6):1086–1090.

[171] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2022.pdf.*

[172] Sex is derived from the Enrollment Database (EDB), and is categorized into male and female. *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2022.pdf.*

[173] Beneficiary age (in years) is measured at the beginning of each month, and is obtained from the Medicare beneficiary birth date variable in the EDB Record Identification Code (RIC) A Table. The following seven age groups are used for all relevant data presentation for this TEP: less than 12, 13–17, 18–44, 45–59, 60–69, 70–79, and 80. *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2022.pdf.*

[174] Section 226A of the Act; 42 CFR 406.13.

[175] ESRD beneficiaries are stratified into four mutually exclusive categories based on their original Medicare entitlement: (1) less than 65 years of age and had both ESRD and disability at time of enrollment; (2) less than 65 years of age and had ESRD at time of enrollment; (3) less than 65 years of age and were disabled at time of enrollment; and (4) those who aged into Medicare (and were diagnosed with ESRD after turning 65). Placeholder for TEP 4 Report.

[176] Beneficiary race and ethnicity information is derived from the Research Triangle Institute (RTI) race algorithm, as obtained from CMS Common Medicare Environment (CME) data. This data provides seven mutually exclusive categories: Non-Hispanic White, Black/African American, Asian or Pacific Islander, Hispanic, American Indian or Alaska Native, and Other/Unknown. Placeholder for TEP 4 Report.

[177] The Core-Based Statistical Area (CBSA) designations are used to determine urban or rural residency status. Beneficiaries whose county of residence is located within a CBSA are deemed urban residents. *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2022.pdf.*

[178] Among Medicare Part D enrollees, Medicare benefit status was derived from monthly enrollment status and low-income status in EDB. Both the beneficiary's dual eligibility status (whether the beneficiary was eligible for both Medicare and Medicaid in a given month) and Premium Subsidy status (whether the beneficiary was receiving any level of premium subsidy in a given month) were considered in determining the beneficiary's Medicare benefit status. *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2022.pdf.*

[179] This result is believed to be due to the fact non-white beneficiaries are more often dually eligible for Medicare and Medicaid compared to White beneficiaries. The low-income subsidies provided to dually eligible beneficiaries gives them the means to enroll in Part D, which is likely why this percentage is slightly higher for non-whites.

[180] ADI is a measure constructed by the Health Resources and Services Administration, and has been validated, refined and adapted by researchers at the University of Wisconsin, Madison, to rank neighborhoods (geographically localized communities within a larger cities, towns, suburbs or rural areas) by socioeconomic disadvantage, specifically factoring in income, education, employment, and housing quality. From these percentile rankings, six mutually exclusive categories of ADI Rankings are constructed with the 1st to 5th percentile being the least disadvantaged and 95th to 100th percentile being most disadvantaged. *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2022.pdf.*

beneficiaries, it is clear that this population represents many individuals who belong to underserved communities, thus there is a need to be vigilant to combat any health disparities that emerge in the ESRD PPS.

b. CMS Activities To Advance Health Equity

The CMS Framework for Health Equity outlines a path to advance health equity that aims to support Quality Improvement Network Quality Improvement Organizations; federal, state, local, and tribal organizations; providers; researchers; policymakers; beneficiaries and their families; and other interested parties in activities to advance health equity.[181] The CMS Framework for Health Equity focuses on five core priority areas which inform our policies and programs: (1) Expand the collection, reporting, and analysis of standardized data; (2) Assess causes of disparities within CMS programs and address inequities in policies and operations to close gaps; (3) Build capacity of health care organizations and the workforce to reduce health and health care disparities; (4) Advance language access, health literacy, and the provision of culturally tailored services and, (5) Increase all forms of accessibility to health care services and coverage.[182] The CMS Quality Strategy [183] and Meaningful Measures Framework [184] also include elimination of disparities as central principles. CMS also requested information in the CY 2022 ESRD PPS proposed rule on revising several related CMS programs to make reporting of health disparities based on social risk factors and race and ethnicity more comprehensive and actionable for ESRD facilities, providers, and patients (86 FR 36362 through 36367).

CMS's efforts aimed at advancing health equity to date have included providing transparency of health disparities, supporting health care providers and health officials with evidence-informed solutions to address social determinants of health and advance health equity, and reporting to providers on gaps in quality. Some of those efforts are:

- The *CMS Mapping Medicare Disparities Tool,* which is an interactive map that identifies areas of disparities and is a starting point to understand and investigate geographic, racial and ethnic differences in health outcomes for Medicare patients.[185]
- The *Rural-Urban Disparities in Health Care in Medicare Report,* which details rural-urban differences in health care experiences and clinical care.[186]
- *The CMS Innovation Center's Accountable Health Communities Model,* which includes standardized collection of health-related social needs data.
- *The Guide to Reducing Disparities,* which provides an overview of key issues related to disparities in readmissions and reviews set of activities that can help hospital leaders reduce readmissions in diverse populations.[187]
- The *Chronic Kidney Disease Disparities: Educational Guide for Primary Care,* which is intended to foster the development of primary care practice teams in order to enhance care for patients who are medically underserved with chronic kidney disease and are at risk of progression of disease or complications. The guide provides information about disparities in the care of patients with chronic kidney disease, presents potential actions that may improve care and suggests other available resources that may be used by primary care practice teams in caring for vulnerable patients.[188]

These efforts are informed by reports by the National Academies of Science, Engineering and Medicine and the Office of the Assistant Secretary for Planning and Evaluation, which have examined the influence of social risk factors on several of our programs.

2. Technical Expert Panel (TEP) Focused on Health Disparities Represented in the ESRD PPS

CMS continues to work with federal and private entities to better collect and leverage data on social determinants of health to improve our understanding of how these factors can be better measured in order to reduce health disparities and advance health equity. We continue to work to improve our understanding of this important issue and to identify policy solutions that achieve the goal of attaining health equity for all patients. One of the efforts demonstrating our ongoing commitment to uncover hidden disparities within the ESRD PPS includes the recently held TEP focused on improving CMS's ability to detect and reduce health disparities for our beneficiaries receiving renal dialysis services.

Over the last several years, CMS has been working towards a potential refinement of the ESRD PPS. This effort has included focused data analysis by CMS and included input of interested parties. Four contractor-led TEPs, each with a focus on different aspects of the ESRD PPS, have been convened. The specific objective for the latest TEP (December 2021) was to gather input from diverse interested parties on health disparities arising among patients who are historically medically underserved and are represented in the ESRD PPS patient populations. The TEP included 16 panelists representing ESRD facilities, nephrologists, patient advocates, and representatives from professional associations and industry groups. The contractor presented results of analysis of health disparities that can be measured by currently collected data. Panelists responded with their interpretations of these results and provided their insights about what they thought were hidden disparities not currently measured. Ideas and suggestions for potential changes to data collection for the ESRD PPS to better measure and potentially reduce health disparities were offered.

CMS is using this CY 2023 ESRD PPS proposed rule to issue an RFI on the topic of health equity issues within the ESRD PPS to obtain input from a broader spectrum of interested parties with a goal of improving CMS's ability to detect and reduce health disparities for our beneficiaries receiving renal dialysis services. The TEP did not provide formal recommendations, but provided discussion items and suggestions in a subsequent report. TEP presentation materials and summary

[181] Centers for Medicare & Medicaid Services Office of Minority Health. The CMS Framework for Health Equity 2022–2032. Available at: *https://www.cms.gov/sites/default/files/2022-04/CMS%20Framework%20for%20Health%20Equity_2022%2004%2006.pdf.*

[182] Centers for Medicare & Medicaid Services Office of Minority Health. Framework for Health Equity 2022–2032. Available at: *https://www.cms.gov/sites/default/files/2022-04/CMS%20Framework%20for%20Health%20Equity_2022%2004%2006.pdf.*

[183] Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[184] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.*

[185] *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH-Mapping-Medicare-Disparities.*

[186] Centers for Medicare & Medicaid Services. Rural-Urban Disparities in Health Care in Medicare. 2019. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Urban-Disparities-in-Health-Care-in-Medicare-Report.pdf.*

[187] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[188] CMS. Chronic Kidney Disease Disparities: Educational Guide for Primary Care. February 2020. Available at: *https://www.cms.gov/files/document/chronic-kidney-disease-disparities-educational-guide-primary-care.pdf.*

reports can be found at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources.*

a. TEP Discussion and Comments From Interested Parties

During the 2021 ESRD PPS TEP, panelists discussed various topics, including the types of direct patient care labor used in renal dialysis care, the case-mix payment adjustment model, subpopulations at risk of health disparities and for whom data are not currently available, and the special case of pediatric patients receiving renal dialysis services. The following is a synopsis of those discussion topics with the exception of pediatric renal dialysis services which is discussed in section II.E.4 of this proposed rule. For a more complete summary, please review the TEP Summary Report.[189]

(1) Direct Patient Care Labor Categories in Dialysis Care

CMS's contractor explained that direct patient care labor categories under the ESRD PPS include social workers, nutritionists, and other staff, but does not include nephrologists, as they are paid separately for their services to dialysis patients. The ESRD facility cost report includes lines for administrative and managerial staff. The base rate can be broken down into a direct patient care labor-related portion and a non-direct patient care labor-related portion, and that the direct patient care labor-related portion is multiplied by the facilities' CBSA wage index for the included job categories. In areas of the country with high wages, the wage index value usually exceeds one, increasing the labor-related portion of the base rate. The current wage index for the ESRD PPS is based on a pre-reclassified acute care hospital wage index and is not derived specifically from ESRD facility cost reports.[190] Panelists and other interested parties have commented that actual direct patient care labor costs associated with providing renal dialysis services are not currently being accurately captured and additional direct patient care labor categories should be explored.

(2) Case-Mix Model

The goal of case mix adjustment is to ensure payment accuracy, meaning payment for a treatment corresponds with expected resource use and cost for that treatment. As noted in the CY 2011 ESRD PPS final rule (75 FR 49034), resources required to furnish routine renal dialysis services such as staff and equipment time vary by patient. Because of the variation in resources required to furnish routine dialysis to individuals with varying patient characteristics, facilities that treat a greater than average proportion of resource-intensive patients could be economically disadvantaged if they are paid a rate based on average resources. In addition, patients who are costlier than average to dialyze may face difficulties gaining access to care because a fixed composite payment rate could create a disincentive to treat such patients. The purpose of a case-mix adjustment based on patient characteristics is to make higher payments to ESRD facilities treating more resource-intensive patients, according to objective quantifiable criteria. To that end, the goal is to protect access to care for the least healthy and most costly beneficiaries and adequately compensate facilities with high proportion of those beneficiaries.

The ESRD PPS also includes a facility level adjustment designed to align ESRD facility resource use with payment. Facility level adjustments account for additional costs that facilities incur resulting from treatment volume, location, and proportion of high cost treatments (75 FR 49116 through 49127). At the facility level, panelists suggested that ESRD facilities located in areas with low physician to patient ratios and in disadvantaged areas also be considered.

Patient Characteristics and Comorbidities

Patient characteristics and comorbidities that best predicted variation in renal dialysis service costs were introduced in the CY 2011 ESRD PPS final rule (75 FR 49034) and revised in the CY 2016 PPS final rule (80 FR 68974 through 68979). The four case-mix adjusters are patient age, body surface area (BSA), low body mass index (BMI) and comorbidities (hereditary hemolytic or sickle cell anemia, myelodysplastic syndromes, gastrointestinal (GI) tract bleeding with hemorrhage, and pericarditis). Panelists noted that BSA and BMI are often correlated. Panelists stated there were other factors they believe were important to include in the case mix adjustment and suggested replacing the current low incidence comorbidities with others. One panelist suggested that upper GI bleeds be removed from the present list of comorbidities in favor of coronary artery disease history, diabetes history, and hypertension. Another panelist offered that respiratory failures should be considered, due to the frequency of this comorbidity they see in their practice. Finally, panelists strongly urged that CMS investigate the direct use of social determinants of health in the case-mix adjustment within the ESRD PPS.

(3) Subpopulations With Observable Disparities in Treatment or Outcomes Related to ESRD

Panelists noted the existence of patient sub-populations for whom data are not currently available that likely experience health disparities with regard to their treatment of ESRD. These include beneficiaries at ESRD facilities with low physician to patient ratios, as a lack of sufficient physician staffing could lead to poor access to care. Panelists also suggested that patients who are experiencing homelessness, undocumented, have limited English proficiency, and those that have mental health issues, should be considered subgroups at risk as well. They noted that many patients fit into more than one of these high-risk subgroups. Some panelists questioned whether the ADI was the best measure of neighborhood disadvantage as it does not consider availability of health resources within neighborhood groupings; however, they did not offer suggestions for any alternative measures.

(4) Payment Accuracy

Payment accuracy, for the purposes of the TEP discussion, was defined as how well ESRD PPS payments are aligned with observed costs for providing dialysis treatment. Panelists largely agreed that there was general alignment of costs and payments through the ESRD PPS, but they noted that there were patient groups and provider types for which payments were inadequate. The focus of these analyses was to explore potential disparities in payment accuracy among patient groups and provider types that might exacerbate health disparities. CMS's contractor presented information on payment accuracy across patient demographic subgroups (including age, sex, race/ethnicity), and facility types (including rural, low volume and geographically isolated facilities; and wage index and facility ownership type.) The panelists discussed at length the relationship between geographic isolation, patient access to care, and resulting costs. Panel members suggested that access to public transportation may be a relatively

[189] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2022.pdf.*

[190] Pre-reclassified wage index in ESRD PPS means that wages for all hospital registered nurses are combined to obtain the CBSA-specific wages for RNs in ESRD facilities.

accurate marker of geographic isolation (defined as the distance between ESRD facilities) in urban areas. They also noted that geographic isolated communities were likely to have few primary care facilities and are also more likely to be ''food deserts.'' The panelists suggested that beneficiaries residing in these areas also experience difficulties in obtaining timely care for other medical conditions, such as diabetes, hypertension, and cardiovascular disease. They further noted that geographic isolation and difficulties in gaining access to care often results in a gaining access to care often results in a renal dialysis patient population with a greater burden of disease. Finally, panelists observed that patients in geographically isolated areas often turned to the renal dialysis facility for their unmet medical care needs. The panelists urged CMS to consider an upward payment adjustment for isolated facilities in areas where low income and low resources drive up the costs of providing care.

The panel focused much of their discussion around patient populations that faced special challenges in access to renal dialysis services and for whom the cost of care was likely higher, but who were not accounted for in current data collection activities under the ESRD PPS. The panel identified some of these patient subgroups to include: patients with housing insecurity as they are ineligible for both organ transplantation and home renal dialysis and thus dialyze in-center indefinitely; patients that are disabled or amputees who may require transfer assistance or extensive wound care; patients in hospice; patients who are not treatment compliant because of limited English proficiency, low health literacy, or behavior or mental health problems.

(5) Incorporation of ESRD PPS Payment Adjustments Based on Social Determinants of Health

Discussions during the December 2021 TEP discussion on SDOH were based on the definition of SDOH referring to non-biological factors that affect health status in a population.[191] The TEP members suggested making greater use of SDOH in the case-mix payment adjustment to help address additional costs associated with caring for patients with underlying social and economic risk factors (including, for example, housing insecurity, language barriers, lack of transportation, etc.) that make getting to and adhering to renal dialysis treatment more difficult and costlier for health care providers.

There are many factors that can contribute to increased costs. One panelist noted that their ESRD facility caseload included patients who were undocumented, experiencing homelessness, and had mental health issues, and these types of issues should be considered in payment models. Panelists strongly suggested that in order to better characterize the factors associated with increased treatment costs for these medically vulnerable and historically underserved patients who are at high-risk for adverse health outcomes, efforts should be made to standardize the collection of SDOH among patients enrolled in the ESRD PPS. They suggested several means of collecting this information including making more extensive use of the SDOH on the 2728 ESRD Medical Evidence Report Form (which is completed at the initiation of renal dialysis services); using SDOH screening tools and embedding them in patient enrollment materials; and using validated third party patient experience surveys. The panelists also suggested that this information be collected using Z codes in Medicare claims so that it could be updated on a regular basis, but cautioned that this would increase reporting burden on the facilities. The panelists also suggested that placing a modifier on claims to indicate the need for intensive resource utilization during renal dialysis services (for example, for amputees) may help better identify these costly patients. Another panelist suggested the focus should be on acting on the data already available instead of collecting more data.

Following the presentation on differences in treatment patterns among subgroups of the ESRD patient population, the panelist discussion focused on the following topics: home renal dialysis services, additional data elements that should be collected, potential payment changes to address disparities, and transportation. Panelists discussed potential reasons for differential use of home renal dialysis modalities and the need to track preventive care measures delivered through the more advanced stages of CKD. They also stated that better data on such patient characteristics as health literacy, English language proficiency, and transportation availability for treatment would help policymakers better understand treatment choices and treatment adherence.

Panelists also discussed treatment frequency and missed treatments in response to data presented by the contractor. While treatment frequencies did not vary significantly across patient race/ethnicity or proxies for income status, the following difference were found for the occurrence of missed treatments: American Indian/Alaska Native and Black/African American beneficiaries, beneficiaries with proxies (Medicare and Medicaid benefits, and ADI ranking) indicating lower socioeconomic status, and beneficiaries living in urban areas.[192] Some panelists suggested that missed treatments be incorporated into the case-mix adjustment; however, it was noted that the overall number of missed treatments is very small, across facility types. CMS data indicated on average, only one tenth of one percent of treatments are missed.

3. Request for Information on Advancing Health Equity Under the ESRD PPS

CMS plans to continue working with health care providers, the public, and other key interested parties on these important issues to identify policy solutions that achieve the goals of attaining health equity for all patients. Specifically, we are requesting comments on improving CMS's ability to detect and reduce health disparities for our beneficiaries receiving renal dialysis services. When responding, please note the question to which your comment is addressing.

Specifically, we are inviting public comment on the following:

- What kind of refinements to the ESRD PPS payment policy could mitigate health disparities and promote health equity?
- Are there specific comorbidities that should be examined when calculating the case-mix adjustment that would help better represent the ESRD population and help address health disparities? Please describe in detail and provide specific data or recommendations for analytical frameworks and data sources that CMS should use in evaluating such comorbidities.
- Are there specific subpopulations whose needs are not adequately accounted for by the current ESRD PPS payment policy and should be evaluated for potential health disparities?
- What are the challenges, and suggested ways to address, defining and collecting accurate and standardized, self-identified demographic information (including information on race and

[191] *https://academic.oup.com/ije/article/35/4/1111/686451.* A reference for social determinants of health can be found at the following website: *https://health.gov/healthypeople/priority-areas/social-determinants-health.*

[192] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-presentation-december-2021.pdf;* slides 77, 78, 80, and 81.

ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, and language preference) for the purposes of reporting, stratifying data by population, and other data collection efforts that would refine ESRD PPS payment policy.

++ What impact do SDOHs have on resource use and treatment costs for patients who are medically underserved?

++ Which SDOHs should data collection include?

++ How should data regarding SDOH be collected? How should such data be used in the ESRD PPS to help mitigate health disparities and promote health equity?

- How can CMS use existing data sources to better identify unmet needs among specific subpopulations that could result in health disparities?
- How can CMS revise case-mix categories in the ESRD PPS to better represent underserved populations?
- Are there actions CMS could potentially consider under the ESRD PPS to help prevent or mitigate potential bias in renal dialysis technologies, treatments, or clinical tools that rely on clinical algorithms? What are the relevant considerations for evaluating the effectiveness of such actions?

While we will not be responding to specific comments submitted in response to this RFI, we intend to use this input to inform future policy development. We look forward to receiving feedback on these topics, and we note that responses to the RFI should focus on how the suggestions could be applied to the ESRD PPS. Data to support any proposed revisions will be extremely important, so please include any data that supports your comments. CMS would propose any potential changes to payment policies through a separate notice and comment rulemaking.

4. Health Disparities Faced by Pediatric Patients Receiving Renal Dialysis Services Within the ESRD PPS

a. Background and Pediatric Dialysis Overview [193]

Compared to the Medicare dialysis adult population, the Medicare dialysis pediatric population is much smaller, comprising approximately 0.14 percent of the total ESRD patient population in 2019. Consequently, only 1.4 percent of ESRD facilities that furnish treatment in 2019 were pediatric facilities,[194] where ''pediatric facilities'' is defined as those providing at least 100 pediatric dialysis treatments in 2019. These facilities are mostly located in urban areas and typically based in a children's hospital or major medical center. Pediatric facilities are also either very small (furnishing less than 4,000 treatments per year) or very large (furnishing at least 10,000 treatments per year). Pediatric facilities also have higher direct patient care labor expenditures than adult facilities. The overall median person-hours of direct patient care labor per treatment in hospital-based facilities in 2019 was one hour more for pediatric facilities than for those serving adult Medicare dialysis patients. Registered nurses and licensed practical nurses contributed roughly double the person-hours toward a pediatric dialysis treatment compared to an adult dialysis treatment.

To examine pediatric dialysis treatment patterns during the TEP, the pediatric dialysis patient population was stratified into two age groups: patients younger than age 13 years old and those ages 13 to 17 years old. Pediatric patients younger than age 13 are more likely to dialyze using home peritoneal dialysis when compared to patients ages 13 to 17 and adults. Use of in-center hemodialysis increases as patients get older, and this modality was the most frequently used for teenagers (aged 13–17) and adults. Lastly, weekly treatment frequency tends to be very similar between the teenage and adult populations. Differences in treatment frequency mainly lie in the 99th percentile of pediatric patients younger than 13 years of age, who receive an average of five in-center hemodialysis sessions per week, a frequency rarely seen in the adult population.

b. TEP Discussion and Comments From Interested Parties

CMS has continued to hear concerns from organizations associated with pediatric dialysis about underpayment of pediatric renal dialysis services under the current ESRD PPS payment model. These organizations emphasize that pediatric renal dialysis services require significantly different staffing and supply needs from those of adults. Most of these organizations agree there is a need for more finely tuned cost data for pediatric dialysis. Many organizations support CMS efforts to explore ways to improve collecting pediatric-specific data to better characterize the necessary resources and associated costs of delivering pediatric ESRD care. During the December 2020 TEP, panelists provided suggestions for the pediatric dialysis payment adjustment.[195] Those ideas were also discussed in the CY 2022 ESRD PPS proposed rule (86 FR 36398; 36402 through 36404). Since pediatric dialysis patients represent the smallest sub-population in the Medicare ESRD PPS, CMS is using this RFI to ask interested parties to comment on health disparities that may exist for this population, and we are requesting input through this RFI on how changes to the ESRD PPS, including changes to data collection procedures, may help reduce any such disparities.

As noted earlier in this RFI, one of the efforts demonstrating CMS' ongoing commitment to closing the health equity gap includes the recently held TEP focused on health disparities represented in the ESRD PPS. See section II.E.2. of this proposed rule for more information about this TEP. The specific objective for this TEP (December 2021) was to gather input from a diverse group of interested parties on health disparities arising among patient groups represented in the ESRD PPS who are historically underserved. Issues regarding the pediatric population were discussed.

Comments from interested parties regarding the payment model for pediatric renal dialysis services have mostly focused on the high total cost of care for pediatric patients. Interested parties also have noted that although pediatric patients disproportionately receive treatment in hospital-based facilities, the hospital cost report (CMS Form 2552–10) does not distinguish between dialysis costs for pediatric and adult populations.

(1) Labor

Interested parties have commented during the TEPs and in response to prior rulemaking that the current collection of information does not account for the amount of staff time and the specialized staffing that is needed to provide care to this population. Many noted that costs unique to pediatric dialysis, such as child life specialists, developmental and behavioral psychologists, pediatric dieticians, and social workers, are not adequately captured in current cost reports or claims, and therefore are not

[193] ESRD TEP Summary Report of TEP held on December 10–11, 2020, p. 18–19. *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf.*

[194] As per the 2020 TEP, 1.4 percent of all ESRD facilities were designated pediatrics, when defining pediatrics as >100 treatments/yr in 2019. See: *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-presentation-december-2020.pdf.*

[195] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf.*

accounted for in pediatric adjustments (86 FR 36402). Commenters have explained that pediatric comorbidities require unique specialized care and that the cost of specialized direct patient care labor and supplies are not captured in the ESRD PPS.

(2) Case Mix

According to data provided by CMS's data contractor, compared to the national average, the ratio of payment relative to cost, standardized relative to the national average for pediatric dialysis treatment was the lowest among ESRD beneficiary age groups. Panelists asserted that the information that is currently collected in the Medicare cost report data do not enable CMS to estimate the true costs of treating pediatric patients. They also assert that key comorbidities for pediatric patient population are not included in case-mix adjustment. Furthermore, there are several challenges in the statistical analysis of pediatric dialysis costs. CMS adjusts the per treatment base rate for pediatric patients to account for patient age and treatment modality (42 CFR 413.235(b)). The small number of patients in this population reduces the precision of statistical models in estimating the true cost of treatment for pediatric dialysis. Another difficulty is disentangling composite rate costs for adult versus pediatric patients from the hospital-based facility cost report data, as these cost reports do not distinguish between adult and pediatric costs.[196]

Commenters have generally supported CMS' efforts to explore ways to improve collecting pediatric-specific data to better characterize the necessary resources and associated costs of delivering pediatric ESRD care. In the CY 2022 ESRD PPS final rule (86 FR 61997), commenters suggested CMS make refinements to better capture costs by examining a breakdown of patient age groups, pediatric-specific dialysis supplies, additional overhead at hospital outpatient ESRD facilities, psychosocial support, specialized pharmacy needs and other costs unique to the pediatric population for home dialysis.

(3) Pediatric Comorbidities

One TEP panelist also noted that the comorbidities currently used in case-mix adjustment do not include those commonly seen in the pediatric population, such as seizure disorders, developmental delays, and congenital anomalies. The panelist and an organization representing pediatric nephrologists suggested other pediatric comorbidities should be considered when calculating the patient level case-mix adjuster. Those comorbidities are:

- Failure to thrive/feeding disorders—80 percent of children under 6 years of age require a G-tube and feeding pump for management of oral aversion or supplemental enteral nutrition to promote growth and ensure appropriate cognitive development;
- Congenital anomalies requiring subspecialty intervention (cardiac, orthopedic, colorectal);
- Congenital bladder/urinary tract anomalies;
- Non-kidney solid organ or stem cell transplant;
- Neurocognitive impairment;
- Global developmental delay;
- Cerebral palsy;
- Seizure disorder;
- Chronic lung disease (including dependency on continuous positive airway pressure machines and ventilators);
- Inability to ambulate or transfer;
- Vision impairment; and
- Feeding tube dependence.

During the discussion about the inability to transfer, inability to ambulate, and needs assistance with daily activities, one panelist noted some centers include these comorbidities for their patients, but others don't because they see them as age-related. For example, a 10-month old shouldn't be expected to ambulate. Therefore, the panel recommend that these conditions also have a designation as age-related which will probably result in more accurate and meaningful data for CMS.

5. Request for Information Regarding Dialysis for Pediatric ESRD Patients

CMS plans to continue working with health care providers, the public, and other key interested parties on these important issues to identify policy solutions that achieve the goals of attaining health equity for all patients. Specifically, we are requesting comments on improving CMS's ability to detect and reduce health disparities within the ESRD PPS payment program for pediatric patients receiving renal dialysis services. When responding, please note the question to which your comment is addressing.

Specifically, we are inviting public comment on the following:

- Please provide any information and supporting documentation about whether there are health disparities in this sub-population.
- How could refinements to the ESRD PPS payment policy mitigate health disparities in the pediatric population?
- Should a pediatric dialysis payment include a specific payment modifier on the claim so that costs for providing pediatric dialysis can be further delineated with alternative payment sub-options (for example, age related or comorbidity related)?
- Are there specific comorbidities that should be examined when calculating the case-mix adjuster that would help better represent the pediatric ESRD population and help address health inequities? Please describe in detail and provide specific data or recommendations for analytical frameworks and data sources that CMS should use in evaluating such conditions.
- Are there other direct patient care labor categories that should be considered when determining the cost to provide renal dialysis services to pediatric patients, and if so, which ones?
- How should CMS revise case-mix categories in the ESRD PPS to better represent the pediatric population?
- Are there SDOH that are specific to the pediatric ESRD population?

While we will not be responding to specific comments submitted in response to this RFI, we intend to use this input to inform future policy development. We look forward to receiving feedback on these topics, and note that responses to the RFI should focus on how the suggestions could be applied to the ESRD PPS. Data to support any proposed revisions will be extremely important, so please include any data that supports your comments. CMS would propose any potential changes to payment policies through a separate notice and comment rulemaking.

III. Calendar Year (CY) 2023 Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

A. Background

The Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27) was enacted on June 29, 2015, and amended the Act to provide coverage and payment for dialysis furnished by an ESRD facility to an individual with acute kidney injury (AKI). Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a subsection (r) to provide

[196] ESRD TEP Summary Report of TEP held on December 10–11, 2020, p. 19. *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf.*

payment, beginning January 1, 2017, for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate, as adjusted by any applicable geographic adjustment applied under section 1881(b)(14)(D)(iv)(II) of the Act and adjusted (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under section 1881(b)(14)(D) of the Act that the Secretary elects.

In the CY 2017 ESRD PPS final rule, we finalized several coverage and payment policies to implement subsection (r) of section 1834 of the Act and the amendments to section 1881(s)(2)(F) of the Act, including the payment rate for AKI dialysis (81 FR 77866 through 77872 and 77965). We interpret section 1834(r)(1) of the Act as requiring the amount of payment for AKI dialysis services to be the base rate for renal dialysis services determined for a year under the ESRD PPS base rate as set forth in § 413.220, updated by the ESRD bundled market basket percentage increase factor minus a productivity adjustment as set forth in § 413.196(d)(1), adjusted for wages as set forth in § 413.231, and adjusted by any other amounts deemed appropriate by the Secretary under § 413.373. We codified this policy in § 413.372 (81 FR 77965).

B. Proposed Annual Payment Rate Update for CY 2023

1. CY 2023 AKI Dialysis Payment Rate

The payment rate for AKI dialysis is the ESRD PPS base rate determined for a year under section 1881(b)(14) of the Act, which is the finalized ESRD PPS base rate, including the applicable annual productivity-adjusted market basket payment update, geographic wage adjustments, and any other discretionary adjustments, for such year. We note that ESRD facilities have the ability to bill Medicare for non-renal dialysis items and services and receive separate payment in addition to the payment rate for AKI dialysis.

As discussed in section II.B.1.d of this proposed rule, the proposed CY 2023 ESRD PPS base rate is $264.09, which reflects the application of the proposed CY 2023 wage index budget-neutrality adjustment factor of 0.999992 and the CY 2023 proposed ESRDB market basket increase of 2.8 percent reduced by the productivity adjustment of 0.4 percentage point, that is, 2.4 percent. Accordingly, we are proposing a CY 2023 per treatment payment rate of $264.09 for renal dialysis services furnished by ESRD facilities to individuals with AKI. This payment rate is further adjusted by the wage index, as discussed in the next section of this proposed rule

2. Geographic Adjustment Factor

Under section 1834(r)(1) of the Act and regulations at § 413.372, the amount of payment for AKI dialysis services is the base rate for renal dialysis services determined for a year under section 1881(b)(14) of the Act (updated by the ESRD bundled market basket and reduced by the productivity adjustment), as adjusted by any applicable geographic adjustment factor applied under section 1881(b)(14)(D)(iv)(II) of the Act. Accordingly, we apply the same wage index under § 413.231 that is used under the ESRD PPS and discussed in section II.B.1.b of this proposed rule. The AKI dialysis payment rate is adjusted by the wage index for a particular ESRD facility in the same way that the ESRD PPS base rate is adjusted by the wage index for that facility (81 FR 77868). Specifically, we apply the wage index to the labor-related share of the ESRD PPS base rate that we utilize for AKI dialysis to compute the wage adjusted per-treatment AKI dialysis payment rate. As stated previously, we are proposing a CY 2023 AKI dialysis payment rate of $264.09, adjusted by the ESRD facility's wage index. We are also proposing that the wage index floor increase discussed in section II.B.1.b.(2) of this proposed rule and the permanent 5-percent cap on wage index decreases discussed in section II.B.1.b.(3) of this proposed rule that we are proposing to apply under the ESRD PPS would apply in the same way to AKI dialysis payments to ESRD facilities.

IV. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

A. Background

For a detailed discussion of the End-Stage Renal Disease Quality Incentive Program's (ESRD QIP's) background and history, including a description of the Program's authorizing statute and the policies that we have adopted in previous final rules, we refer readers to the following final rules:

- CY 2011 ESRD PPS final rule (75 FR 49030);
- CY 2012 ESRD PPS final rule (76 FR 628);
- CY 2012 ESRD PPS final rule (76 FR 70228);
- CY 2013 ESRD PPS final rule (77 FR 67450);
- CY 2014 ESRD PPS final rule (78 FR 72156);
- CY 2015 ESRD PPS final rule (79 FR 66120);
- CY 2016 ESRD PPS final rule (80 FR 68968);
- CY 2017 ESRD PPS final rule (81 FR 77834);
- CY 2018 ESRD PPS final rule (82 FR 50738);
- CY 2019 ESRD PPS final rule (83 FR 56922);
- CY 2020 ESRD PPS final rule (84 FR 60648);
- CY 2021 ESRD PPS final rule (85 FR 71398); and
- CY 2022 ESRD PPS final rule (86 FR 61874).

We have also codified many of our policies for the ESRD QIP at 42 CFR 413.177 and § 413.178.

B. Flexibilities for the ESRD QIP in Response to the Public Health Emergency (PHE) Due to COVID–19

1. Measure Suppression Policy for the Duration of the COVID–19 PHE

In the CY 2022 ESRD PPS final rule, we finalized a measure suppression policy for the duration of the COVID–19 Public Health Emergency (PHE) (86 FR 61910 through 61913). We stated that we had previously identified the need for flexibility in our quality programs to account for the impact of changing conditions that are beyond participating facilities' control. We identified this need because we would like to ensure that facilities are not affected negatively when their quality performance suffers not due to the care provided, but due to external factors, such as the COVID–19 PHE.

Specifically, we finalized a policy for the duration of the PHE for COVID–19 that enables us to suppress the use of measure data for scoring and payment adjustments if we determine that circumstances caused by the COVID–19 PHE have affected the measures and the resulting Total Performance Scores (TPSs) significantly. We also finalized the adoption of Measure Suppression Factors which will guide our determination of whether to suppress an ESRD QIP measure for one or more program years where the baseline or performance period of the measure overlaps with the PHE for COVID–19. The finalized Measure Suppression Factors are as follows:

- Measure Suppression Factor 1: Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years.
- Measure Suppression Factor 2: Clinical proximity of the measure's

focus to the relevant disease, pathogen, or health impacts of the COVID–19 PHE.

• Measure Suppression Factor 3: Rapid or unprecedented changes in:

++ clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or

++ the generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin.

• Measure Suppression Factor 4: Significant national shortages or rapid or unprecedented changes in:

++ healthcare personnel;

++ medical supplies, equipment, or diagnostic tools or materials; or

++ patient case volumes or facility-level case mix.

We also stated that we would still provide confidential feedback reports to facilities on their measure rates on all measures to ensure that they are made aware of the changes in performance rates that we have observed. We also stated that we would publicly report suppressed measure data with appropriate caveats noting the limitations of the data due to the PHE for COVID–19. We strongly believe that publicly reporting these data would balance our responsibility to provide transparency to consumers and uphold safety while ensuring that hospitals are not unfairly scored or penalized through payment under the ESRD QIP.

We are not proposing any changes to the measure suppression policy in this proposed rule.

2. Proposals To Suppress Six ESRD QIP Measures for PY 2023

a. Background

COVID–19 has had significant negative health effects—on individuals, communities, nations, and globally. Consequences for individuals who have COVID–19 include morbidity, hospitalization, mortality, and post-COVID conditions (also known as long COVID). As of early March 2022, over 78 million COVID–19 cases, 4.5 million new COVID–19 related hospitalizations, and 900,000 COVID–19 deaths have been reported in the U.S.[197] Provisional life expectancy data for CY 2020 showed that COVID–19 reduced life expectancy by 1.5 years overall, with the estimated impact disproportionately affecting minority communities.[198] According to this analysis, the estimated life expectancy reduction for Black and Latino populations is three times the estimate when comparing to the white population.[199] With a death toll surpassing that of the 1918 influenza pandemic, COVID–19 is the deadliest disease in American history.[200]

Additionally, impacts of the pandemic continued to accelerate in 2021 as compared with 2020. The Delta variant of COVID–19 (B.1.617.2) surfaced in the United States in early-to-mid 2021. Studies have shown that the Delta variant was up to 60 percent more transmissible than the previously dominant Alpha variant in 2020.[201] Further, in November 2021, the number of COVID–19 deaths for 2021 surpassed the total deaths for 2020. According to Center for Disease Control and Prevention (CDC) data, the total number of deaths involving COVID–19 reached 385,453 in 2020 and 451,475 in 2021.[202] With this increased transmissibility and morbidity associated with the Delta variant, we remain concerned about using measure data that is significantly impacted by COVID–19 for scoring and payment purposes for the PY 2023 program year.

In the CY 2022 ESRD PPS final rule, we finalized the suppression of the following measures for the PY 2022 program year:

- Standardized Hospitalization Ratio (SHR) clinical measure
- Standardized Readmission Ratio (SRR) clinical measure
- Long-Term Catheter Rate clinical measure
- In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration clinical measure

Since the publication of the CY 2022 ESRD PPS final rule, we have conducted analyses on all ESRD QIP measures to determine whether and how COVID–19 has impacted the validity of the data used to calculate these measures for PY 2023. Our findings from these analyses are discussed below. Based on those analyses, we are proposing to suppress the following measures for PY 2023:

- SHR clinical measure (under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years);
- SRR clinical measure (under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years);
- Long-Term Catheter Rate clinical measure (under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years);
- In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration clinical measure (under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years; and Measure Suppression Factor 4, Significant national shortages or rapid or unprecedented changes in:

++ healthcare personnel; or

++ patient case volumes or facility-level case mix);

- Percentage of Prevalent Patients Waitlisted (PPPW) clinical measure (under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years; and Measure Suppression Factor 4, Significant national shortages or rapid or unprecedented changes in:

++ patient case volumes or facility-level case mix); and

- Kt/V Dialysis Adequacy clinical measure (under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could

[197] *https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/index.html.*

[198] Arias E, Tejada-Vera B, Ahmad F, Kochanek KD. Provisional life expectancy estimates for 2020. Vital Statistics Rapid Release; no 15. Hyattsville, MD: National Center for Health Statistics. July 2021. DOI: *https://dx.doi.org/10.15620/cdc:107201.*

[199] Andrasfay, T., & Goldman, N. (2021). Reductions in 2020 US life expectancy due to COVID–19 and the disproportionate impact on the Black and Latino populations. Proceedings of the National Academy of Sciences of the United States of America, 118(5), e2014746118. *https://www.pnas.org/content/118/5/e2014746118.*

[200] Branswell, Helen. Covid overtakes 1918 Spanish flu as deadliest disease in U.S. history. STAT. September 20, 2021. Available at: *https://www.statnews.com/2021/09/20/covid-19-set-to-overtake-1918-spanish-flu-as-deadliest-disease-in-american-history/.*

[201] Allen H, Vusirikala A, Flannagan J, et al. Increased Household Transmission of COVID–19 cases associated with SARS–CoV–2 Variant of Concern B.1.617.2: a national case-control study. Public Health England. 2021.

[202] *https://www.cdc.gov/nchs/nvss/vsrr/covid19/index.htm.*

be significantly better or significantly worse compared to historical performance during the immediately preceding program years).

In the CY 2021 ESRD PPS final rule, we finalized that the mTPS for PY 2023 would be 57, and also finalized an associated payment reduction scale (85 FR 71471). However, as discussed below, we are proposing in this proposed rule to update the mTPS and payment reduction scale to reflect our proposal to suppress six measures for PY 2023, which is almost half of the current ESRD QIP measure set. We are also proposing to amend 413.178(a)(8) to state that the definition of the mTPS does not apply to PY 2023. The measures that we are proposing to score for PY 2023 are the Clinical Depression Screening and Follow-Up reporting measure, the Standardized Fistula Rate clinical measure, the Hypercalcemia clinical measure, the Standardized Transfusion Ratio (STrR) reporting measure, the Ultrafiltration Rate reporting measure, the Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) reporting measure, the National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) clinical measure, and the NHSN Dialysis Event reporting measure. The proposed re-calculated mTPS for PY 2023 would be 80. If one or more of our measure suppression proposals is not finalized, then we would to revise the mTPS for PY 2023 so that it includes all measures that we finalize for scoring for PY 2023. We are also proposing to codify these proposals in our regulations by adding a new 413.178(i), which specifies that we will calculate a measure rate for each of the suppressed measures, but will not score facility performance on those suppressed measures or include them in the facility's TPS for PY 2023. Proposed 413.178(i) would also define the mTPS for PY 2023 as the total performance score that an ESRD facility would receive if, during the baseline period, it performed at the 50th percentile of national ESRD facility performance on the measures described in proposed 413.178(i)(2). As discussed in section IV.C of this proposed rule, we are also proposing to calculate the performance standards for PY 2023 using CY 2019 data, and are proposing to revise our regulations at 413.178(d)(2) to reflect this proposal.

We continue to be concerned about the impact of the COVID–19 PHE, but we are encouraged by the rollout of COVID–19 vaccinations and treatment for those diagnosed with COVID–19 and we believe that facilities are better prepared to treat patients with COVID–19. Our measure suppression policy focuses on a short-term, equitable approach during this unprecedented PHE, and was not intended for indefinite application. Additionally, we want to emphasize the long-term importance of incentivizing quality care tied to payment. The ESRD QIP is an example of our long-standing effort to link payments to healthcare quality in the dialysis facility setting.[203]

We understand that the COVID–19 PHE is ongoing and unpredictable in nature, however, we believe that 2022 has a more promising outlook in the fight against COVID–19. As we enter the third year of the pandemic, healthcare providers have gained experience managing the disease, surges of COVID–19 infection, and adjusting to supply chain fluctuations. In 2022 and the upcoming years, we anticipate continued availability and increased uptake in the use of vaccinations,[204] including the availability and use of vaccination for young children ages 5 to 11, who were not eligible for vaccination for the majority of 2021 and for whom only 32 percent had received at least one dose as of February 23, 2022.[205] [206] Additionally, FDA has expanded availability of at-home COVID–19 treatment, having issued the first emergency use authorizations (EUAs) for two oral antiviral drugs for the treatment of COVID–19 in December 2021.[207] [208] Finally, the Biden-Harris Administration has mobilized efforts to distribute home test kits,[209] N–95 masks,[210] and increase COVID–19 testing in schools,[211] providing more treatment and testing to the American people. Therefore, our goal is to continue resuming the use of all measure data for scoring and payment adjustment purposes beginning with the PY 2024 ESRD QIP. That is, for PY 2024, for each facility, we would plan to calculate measure scores for all of the measures in the ESRD QIP measure set for which the facility reports the minimum number of cases. We would then calculate a TPS for each eligible facility and use the established methodology to determine whether the facility would receive a payment reduction for the given payment year. We understand that the PHE for COVID–19 is ongoing and unpredictable in nature, and we would continue to assess the impact of the PHE on measure data used for the ESRD QIP.

b. Proposal To Suppress the SHR Clinical Measure for PY 2023

In this proposed rule, we are proposing to suppress the SHR clinical measure for PY 2023 program year under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse as compared to historical performance during the immediately preceding program years. We refer readers to the CY 2022 ESRD PPS final rule for previous analysis on the impact of the COVID–19 PHE on SHR clinical measure performance (86 FR 61914 through 61915). The SHR clinical measure is an all-cause, risk-standardized rate of hospitalizations during a 1-year observation window. The standardized hospitalization ratio is

[203] CMS has also partnered with the CDC in a joint Call to Action on safety, which is focused on our core goal to keep patients safe. Fleisher et al. (2022). *New England Journal of Medicine.* Article available here: *https://www.nejm.org/doi/full/10.1056/NEJMp2118285?utm_source=STAT+Newsletters&utm_campaign=8933b7233e-MR_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-8933b7233e-151759045.*

[204] Schneider, E. et al. (2022). *The Commonwealth Fund.* Responding to Omicron: Aggressively Increasing Booster Vaccinations Now Could Prevent Many Hospitalizations and Deaths. Available at: *https://www.commonwealthfund.org/blog/2022/responding-omicron.*

[205] KFF, Update on COVID–19 Vaccination of 5–11 Year Olds in the U.S., *https://www.kff.org/coronavirus-covid-19/issue-brief/update-on-covid-19-vaccination-of-5-11-year-olds-in-the-u-s/.*

[206] *https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/children-and-covid-19-vaccination-trends/.*

[207] U.S. Food and Drug Administration. (2021). Coronavirus (COVID–19) Update: FDA Authorizes First Oral Antiviral for Treatment of COVID–19. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-oral-antiviral-treatment-covid-19.*

[208] U.S. Food and Drug Administration. (2021). Coronavirus (COVID–19) Update: FDA Authorizes Additional Oral Antiviral for Treatment of COVID–19 in Certain Adults. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-oral-antiviral-treatment-covid-19-certain#:~:text=Today%2C%20the%20U.S.%20Food%20and,progression%20to%20severe%20COVID%2D19%2C.*

[209] The White House. (2022). Fact Sheet: The Biden Administration to Begin Distributing At-Home, Rapid COVID-19 Tests to Americans for Free. Available at: *https://www.whitehouse.gov/briefing-room/statements-releases/2022/01/14/fact-sheet-the-biden-administration-to-begin-distributing-at-home-rapid-covid-19-tests-to-americans-for-free/.*

[210] Miller, Z. 2021. *The Washington Post.* Biden to give away 400 million N95 masks starting next week Available at: *https://www.washingtonpost.com/politics/biden-to-give-away-400-million-n95-masks-starting-next-week/2022/01/19/5095c050-7915-11ec-9dce-7313579de434_story.html.*

[211] The White House. (2022). FACT SHEET: Biden-Harris Administration Increases COVID-19 Testing in Schools to Keep Students Safe and Schools Open. Available at: *https://www.whitehouse.gov/briefing-room/statements-releases/2022/01/12/fact-sheet-biden-harris-administration-increases-covid-19-testing-in-schools-to-keep-students-safe-and-schools-open/.*

defined as the ratio of the number of hospital admissions that occur for Medicare ESRD dialysis patients treated at a particular facility to the number of hospitalizations that would be expected given the characteristics of the facility's patients and the national norm for facilities. This measure is calculated as a ratio but can also be expressed as a rate. The intent of the SHR clinical measure is to improve health care delivery and care coordination to help reduce unplanned hospitalization among ESRD patients.

Based on our analysis of Medicare dialysis patient data from January 2021 through September 2021, we found that hospitalizations involving patients diagnosed with COVID–19 resulted in higher mortality rates, higher rates of discharge to hospice or skilled nursing facilities, and lower rates of discharge to home than hospitalizations involving patients who were not diagnosed with COVID–19. Specifically, the hospitalization rate for Medicare dialysis patients diagnosed with COVID–19 was up to three times greater than the hospitalization rate during the same period for Medicare dialysis patients who were not diagnosed with COVID–19, which is much greater than the relative risk of hospitalization for any other comorbidity. Similar to our analysis in the CY 2022 ESRD PPS final rule (86 FR 61915), we believe that this indicates that COVID–19 has had a significant impact on the hospitalization rate for dialysis patients. Because COVID–19 Medicare dialysis patients are at significantly greater risk of hospitalization, and the SHR clinical measure was not developed to account for the impact of COVID–19 on this patient population, we continue to be concerned about the effects of the observed COVID–19 hospitalizations on the SHR clinical measure. We also note that the waves of the Delta and Omicron variants during 2021 affected different regions of the country at different rates depending on factors like time of year, geographic density, state and local policies, and health care system capacity.[212] [213] Because of the increased hospitalization risk associated with COVID–19 and the Medicare dialysis patient population, we are concerned that these regional differences in COVID–19 rates have led to distorted hospitalization rates such that we could not reliably make national, side-by-side comparisons of facility performance on the SHR clinical measure.

We also analyzed data from January 2020 through September 2021, which indicates that hospitalization [214] and mortality rates [215] were 6 times higher in the ESRD population. Although our measure suppression analysis focuses on CY 2020 and CY 2021 data and we only have partial CY 2021 data available at this time, we believe that the remaining 2021 data will continue to show similar trends. Not only are there effects on patients diagnosed with COVID–19, but our data indicates that the presence of the virus continued to strongly affect hospital admission patterns of dialysis patients through September 2021 and we believe that similar effects will be seen in October through December 2021 data.

Following emergence of the Delta variant in 2021, we have also observed disproportionate increases in COVID–19 cases and related deaths among ESRD beneficiaries. Similarly, emergence of the Omicron variant in December 2021 was followed by another mortality spike. Because the COVID–19 pandemic generally, and the Delta and Omicron waves specifically, swept through geographic regions of the country unevenly, we are additionally concerned that facilities in different regions of the country would have been affected differently throughout 2021, thereby skewing measure performance and affecting national comparability. Based on the impact of COVID–19 on SHR results, including the continued deviation in measurement, we believe that the SHR clinical measure meets our criteria for Factor 1 where performance data would significantly deviate from historical data performance and would be considered unreliable. Therefore, we believe that the resulting performance measurement on the SHR clinical measure would not be sufficiently reliable or valid for use in the ESRD QIP for scoring and payment adjustment purposes.

We believe that the SHR clinical measure is an important part of the ESRD QIP measure set. However, we are concerned that the COVID–19 PHE would continue affecting measure performance on the current SHR clinical measure such that we would not be able to score facilities fairly or equitably on it for PY 2023. However, we are proposing to continue to collect the measure's claims data from participating facilities so that we can monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We also propose to continue providing confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We intend to publicly report PY 2023 data where feasible and appropriately caveated.

In the CY 2022 ESRD PPS final rule, we stated that we were currently exploring ways to adjust effectively for the systematic effects of the COVID–19 PHE on hospital admissions for the SHR clinical measure (86 FR 61915). We discuss our technical specifications update to the SHR clinical measure to risk-adjust for patients with a history of COVID–19 in section IV.B.3 of this proposed rule.

We welcome public comment on our proposal to suppress the SHR clinical measure for PY 2023.

c. Proposal To Suppress the SRR Clinical Measure for PY 2023

In this proposed rule, we are proposing to suppress the SRR clinical measure for the PY 2023 program year under Measure Suppression Factor 1, significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years. We refer readers to the CY 2022 ESRD PPS final rule for previous analysis on the impact of the COVID–19 PHE on SRR clinical measure performance (86 FR 61915 through 61916). The SRR clinical measure assesses the number of readmission events for the patients at a facility, relative to the number of readmission events that would be expected based on overall national rates and the characteristics of the patients at that facility as well as the number of discharges. The intent of the SRR clinical measure is to improve care coordination between ESRD facilities and hospitals to improve communication prior to and post discharge.

Based on our analysis, we have found that index discharge hospitalizations involving dialysis patients diagnosed

[212] Cuadros DF, Miller FD, Awad S, Coule P, MacKinnon NJ. Analysis of Vaccination Rates and New COVID–19 Infections by US County, July–August 2021. *JAMA Netw Open.* 2022;5(2):e2147915. doi:10.1001/jamanetworkopen.2021.47915

[213] Iuliano AD, Brunkard JM, Boehmer TK, et al. Trends in Disease Severity and Health Care Utilization During the Early Omicron Variant Period Compared with Previous SARS–CoV–2 High Transmission Periods—United States, December 2020–January 2022. MMWR Morb Mortal Wkly Rep 2022;71:146–152. DOI: *http://dx.doi.org/10.15585/mmwr.mm7104e4external* icon.

[214] *https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-services-through-2021-08-21.pdf.*

[215] Turgutalp, K., Ozturk, S., Arici, M. et al. Determinants of mortality in a large group of hemodialysis patients hospitalized for COVID–19. BMC Nephrol 22, 29 (2021). *https://doi.org/10.1186/s12882-021-02233-0.*

with COVID–19 resulted in lower readmissions and higher mortality rates within the first 7 days in 2021. We used index hospitalizations occurring from January 2020 through August 2021 to identify eligible index hospitalizations and unplanned hospital readmissions. Focusing on the partial year data for 2021, we found that total hospital readmissions, average number of index discharges, and average number of readmissions were lower than in full-year data for 2018 and 2019. We note that our analysis of 2020 data revealed that overall average readmission rates were similar to pre-COVID years, but that hospitalization in COVID–19 patients resulted in very different outcomes, with increased in-hospital and early post-discharge death and increased discharge to subacute rehabilitation facilities. Although our measure suppression focuses on CY 2021 data and we only have partial CY 2021 data available at this time, we believe that the remaining 2021 data will continue to show similar trends. Our analysis of partial year data for 2021 found that average re-admission rates were slightly lower overall compared to 2018 and 2019. Although we are still analyzing the data for 2021, we believe that similar to 2020, these competing outcomes of index hospitalization continue to have a significant effect on readmission rates, affecting interpretation of hospitalization outcomes between COVID-associated and non-COVID events. Based on this demonstrated association between recent COVID–19 infection and altered patterns of hospitalization and readmission compared to those for non-infected ESRD patients, we remain concerned about the effects of these observations on the calculations for the SRR clinical measure. We note that our preliminary analyses only looked at data through August 2021, which would not fully capture readmission data from the Delta or Omicron surges of the COVID–19 PHE. Based on the impact of COVID–19 on SRR results, including the continued deviation in measurement, we believe that the SRR clinical measure meets our criteria for Factor 1 where performance data would significantly deviate from historical data performance and would be considered unreliable. Therefore, we believe that the resulting performance measurement on the SRR clinical measure would not be sufficiently reliable or valid for use in the PY 2023 ESRD QIP for scoring and payment adjustment purposes.

We believe that the SRR clinical measure is an important part of the ESRD QIP Program measure set. However, we remain concerned that the PHE for the COVID–19 pandemic continues to affect measure performance on the current SRR clinical measure such that we would not be able to score facilities fairly or equitably on it for PY 2023. Additionally, we propose continuing to collect the measure's claims data from participating facilities so that we can monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We would also continue to provide confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We intend to publicly report PY 2023 data where feasible and appropriately caveated.

In the CY 2022 ESRD PPS final rule, we stated that we were currently exploring ways to adjust effectively for the systematic effects of the COVID–19 PHE on hospital admissions for the SRR clinical measure (86 FR 61916). We discuss our technical specifications update to the SRR clinical measure to risk-adjust for patients with a history of COVID–19 in section IV.B.3 of this proposed rule.

We welcome public comment on our proposal to suppress the SRR clinical measure for PY 2023.

d. Proposal To Suppress the Long-Term Catheter Rate Clinical Measure for PY 2023

In this proposed rule, we are proposing to suppress the Long-Term Catheter Rate clinical measure for PY 2023 program year under Measure Suppression Factor 1, significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse as compared to historical performance during the immediately preceding program years. We refer readers to the CY 2022 ESRD PPS final rule for previous analysis on the impact of the COVID–19 PHE on the Long-Term Catheter Rate clinical measure for PY 2022 (86 FR 61917).

In the CY 2018 ESRD PPS final rule, we finalized the inclusion of the Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure in the ESRD QIP measure set beginning with the PY 2021 program (82 FR 50778). The Long-Term Catheter Rate clinical measure is defined as the percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access. The measure is based on vascular access data reported in CMS' ESRD Quality Reporting System (EQRS) (previously, CROWNWeb) and excludes patient-months where a patient has a catheter in place and has a limited life expectancy. The measure evaluates the vascular access type used to deliver hemodialysis. The intent of the Long-Term Catheter Rate clinical measure is to improve health care delivery and patient safety.

Our analysis based on the available data indicated that long-term catheter use rates increased significantly during the COVID–19 PHE. Average long-term catheter rates were averaging around 12 percent during the period CY 2017 through early CY 2020. As we noted in the CY 2022 ESRD PPS final rule, we observed an increase in long-term catheter rates during the pandemic in CY 2020, with rates reaching a peak of 14.7 percent in June 2020 and declining slightly to 14.3 percent in July and August 2020 (86 FR 61917). After remaining around 12 percent for 3 consecutive years, in the CY 2022 ESRD PPS final rule we stated that we view a sudden 2 percent increase in average long-term catheter rates as a significant deviation compared to historical performance during immediately preceding years (86 FR 61917). Since then, we have observed a steady rate increase throughout CY 2021, with unadjusted catheter rates reaching a peak of 17.9 percent in September 2021. By contrast, the unadjusted catheter rates in CY 2019 peaked at 12 percent. We believe that the steep increase in catheter rates during CY 2021 indicates a significant deviation in performance on the Long-Term Catheter Rate clinical measure. We are concerned that the COVID–19 PHE continues to impact the ability of ESRD patients to seek treatment from medical providers regarding their catheter use, either due to difficulty accessing treatment due to COVID–19 precautions at healthcare facilities, or due to increased patient reluctance to seek medical treatment because of risk of COVID–19 precautions at healthcare facilities, or due to increased patient reluctance to seek medical treatment because of risk of COVID–19 exposure and increased associated health risks, and that these contributed to the significant increase in long-term catheter use rates.

We believe that the Long-Term Catheter Rate clinical measure is an important part of the ESRD QIP measure set. However, we are concerned that the PHE for COVID–19 affected measure performance on the current Long-Term Catheter Rate clinical measure such that we would not be able to score facilities fairly or equitably on it for PY 2023. Additionally, participating facilities

would continue to report the measure's data to CMS so that we could monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We would also continue to provide confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We also intend to publicly report PY 2023 data where feasible and appropriately caveated.

We welcome public comment on our proposal to suppress the Long-Term Catheter Rate clinical measure for PY 2023.

e. Proposal To Suppress the ICH CAHPS Clinical Measure for PY 2023

We are proposing to suppress the ICH CAHPS measure for the PY 2023 program year under Measure Suppression Factor 1, significant deviation in national performance on the measure during the PHE for COVID–19, which could be significantly better or significantly worse as compared to historical performance during the immediately preceding program years and Measure Suppression Factor 4, significant national shortages or rapid or unprecedented changes in healthcare personnel and patient case mix. We would calculate facilities' ICH CAHPS measure rates, but we would not use these measure rates to generate achievement or improvement points for this measure. Participating facilities would continue to report the measure data to CMS so that we can monitor the effect of the circumstances on quality measurement and consider appropriate policies in the future. We would continue to provide confidential feedback reports to facilities as part of program activities to allow facilities to track the changes in performance rates that we observe. We also intend to publicly report CY 2021 measure rate data where feasible and appropriately caveated. As noted in section IV.B.1 of this proposed rule, we believe that publicly reporting suppressed measure data is an important step in providing transparency and upholding the quality of care and safety for consumers.

In the CY 2022 ESRD PPS final rule (86 FR 61916 through 61917), we finalized our proposal to suppress the ICH CAHPS clinical measure for the PY 2022 program year under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years. Based on our analysis of CY 2020 ICH CAHPS data, we finalized our proposal to suppress the ICH CAHPS clinical measure for PY 2022 because we found a significant decrease in response scores as compared to previous years. Our most recent analysis that includes Spring 2021 ICH CAHPS data shows a continued deviation in ICH CAHPS scores.

The ICH CAHPS clinical measure is scored based on three composite measures and three global ratings.[216] Global ratings questions employ a scale of 0 to 10, worst to best; each of the questions within a composite measure use either ''Yes'' or ''No'' responses, or response categories ranging from ''Never'' to ''Always'' to assess the patient's experience of care at a facility. Facility performance on each composite measure is determined by the percent of patients who choose ''top-box'' responses (that is, most positive or ''Always'') to the ICH CAHPS survey questions in each domain. The ICH CAHPS survey is administered twice yearly, once in the spring and once in the fall.

Our most recent data indicates that, although the number of participating facilities that submitted data has increased from pre-COVID–19 levels, the number of completed interviews has dropped dramatically. For example, in Spring and Fall 2019, facilities reported 98,868 and 96,255 completed interviews, respectively. By contrast, in Spring and Fall 2021, only 82,987 and 61,930 completed interviews were submitted, respectively. In other words, although a larger number of facilities are submitting ICH CAHPS data, fewer patients within each of those facilities are completing interviews and, as a result, a fewer number of facilities are meeting the survey minimum to be included in the measure for ESRD QIP scoring purposes because of the continuing impact of the PHE.

We believe that these data may also reflect a rapid and unprecedented change in healthcare personnel, as staffing shortages may have had an impact on some of the top box rating scores.

During the course of the PHE, an unprecedented number of healthcare personnel have left the workforce or ended their employment in healthcare settings.[217] This healthcare personnel shortage worsened in 2021, with hospitals across the United States reporting 296,466 days of critical staffing shortages, an increase of 86 percent from the 159,320 days of critical staffing shortages hospitals reported in 2020.[218] Although there is no specific data regarding the healthcare personnel shortages in facilities, reports indicate that facilities have experienced similar staffing shortages.[219] Healthcare workers, especially those in areas with higher infection rates, have reported serious psychological symptoms, including anxiety, depression, and burnout.[220] [221]

Additionally, reports of staff shortages have varied widely geographically. In January 2021, half of the hospitals in New Mexico and over 40 percent of the hospitals in Vermont, Rhode Island, West Virginia, and Arizona reported staffing shortages.[222] Conversely, in that same week, less than 10 percent of hospitals in Washington, DC, Connecticut, Alaska, Illinois, New York, Maine, Montana, Idaho, Texas, South Dakota, and Utah reported staffing shortages. We believe that these staffing shortages reported by hospitals are

[216] Groupings of questions and composite measures can be found at *https://ichcahps.org/Portals/0/SurveyMaterials/ICH_Composites_English.pdf.*

[217] Health Affairs, *COVID–19's Impact on Nursing Shortages, The Rise of Travel Nurses, and Price Gouging* (Jan. 28, 2022), *https://www.healthaffairs.org/do/10.1377/forefront.20220125.695159/.*

[218] *https://healthdata.gov/Hospital/COVID-19-Reported-Patient-Impact-and-Hospital-Capa/g62h-syeh.*

[219] National Kidney Foundation, *COVID–19 and its Impact on Kidney Patients Utilizing U.S. Dialysis Centers* (Jan. 18, 2022), *https://www.kidney.org/news/covid-19-and-its-impact-kidney-patients-utilizing-u-s-dialysis-centers.* See also, Becker's Hospital Review, *Supply shortages disrupt dialysis care in Texas* (Jan. 28, 2022), *https://www.beckeshospitalreview.com/supply-chain/supply-shortages-disrupt-dialysis-care-in-texas.html.* WBIW, *Pandemic causing supply shortages for dialysis patients, staffing shortage for providers* (Feb. 22, 2022), *https://www.wibw.com/2022/02/22/pandemic-causing-supply-shortages-dialysis-patients-staffing-shortage-providers/.* Spectrum News, Worker shortage sends dialysis patients scrambling for treatment (October 4, 2021), *https://spectrumlocalnews.com/nys/hudson-valley/news/2021/10/01/worker-shortage-sends-dialysis-patients-scrambling-for-treatment.*

[220] Kriti Prasad, Colleen McLoughlin, Martin Stillman, Sara Poplau, Elizabeth Goelz, Sam Taylor, Nancy Nankivil, Roger Brown, Mark Linzer, Kyra Cappelucci, Michael Barbouche, Christine A. Sinsky. Prevalence and correlates of stress and burnout among U.S. healthcare workers during the COVID–19 pandemic: A national cross-sectional survey study. EClinicalMedicine, Volume 35. 2021. 100879. ISSN 2589–5370. *https://doi.org/10.1016/j.eclinm.2021.100879.*

[221] Vizheh, M., Qorbani, M., Arzaghi, S.M. *et al.* The mental health of healthcare workers in the COVID–19 pandemic: A systematic review. *J Diabetes Metab Disord* 19, 1967–1978 (2020). *https://doi.org/10.1007/s40200-020-00643-9.*

[222] U.S. News, States With the Biggest Hospital Staffing Shortages (Jan. 13, 2022), *https://www.usnews.com/news/health-news/articles/2022-01-13/states-with-the-biggest-hospital-staffing-shortages* (citing data from the HHS, CDC, and Assistant Secretary for Preparedness and Response Community Profile Report, updated frequently and available here: *https://healthdata.gov/Health/COVID-19-Community-Profile-Report/gqxm-d9w9*).

similar to those experienced by facilities, and that the shortages experienced by ESRD facilities may be even worse due to the highly specialized nature of nephrology staff. Given the wide variance in reported staffing shortages, and the impact staffing shortages may have on ICH CAHPS top box rating scores, we believe our proposal to suppress the ICH CAHPS measure fairly addresses the geographic disparity in the impact of the COVID–19 PHE on participating facilities.

Due to the emergence of COVID–19 variants, such as the Delta and Omicron variants that have arisen from COVID–19 and our belief that facilities have experienced worsening staffing shortages in Q3 and Q4 2021,[223] [224] we anticipate that Fall 2021 data would continue to demonstrate a deviation in national performance such that scoring this measure would not allow us to reliably make national, side-by-side comparisons of facility performance on the ICH CAHPS measure. We believe that suppressing this measure for the PY 2023 would address concerns about the potential unintended consequences of penalizing facilities for deviations in measure performance resulting from the impact of the COVID–19 PHE.

Therefore, we are proposing to suppress the ICH CAHPS measure for the PY 2023 ESRD QIP under Measure Suppression Factors 1 and 4.

We welcome public comment on this proposal.

f. Proposal To Suppress the PPPW Clinical Measure for PY 2023

In this proposed rule, we are proposing to suppress the PPPW clinical measure for PY 2023 under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse as compared to historical performance during the immediately preceding program years, as well as under Measure Suppression Factor 4, significant national shortages or rapid or unprecedented changes in patient case volumes or facility-level case mix.

The PPPW clinical measure is a process measure that assesses the percentage of patients at each facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period. Given the importance of kidney transplantation to patient survival and quality of life, as well as the variability in waitlist rates among facilities, we adopted the PPPW clinical measure in the CY 2019 ESRD PPS final rule to encourage facilities to coordinate care with transplant centers to waitlist patients (83 FR 57003 through 57008).

In the CY 2022 ESRD PPS final rule (86 FR 61914), several commenters recommended that CMS suppress the PPPW clinical measure, noting that the COVID–19 PHE had a significant negative impact on transplant surgeries, referrals, and waitlists, as well as other related areas. A few commenters also noted that waitlist additions significantly decreased during the COVID–19 PHE. At the time, we responded that our analysis of the relevant data available at the time of the proposed rule indicated temporal declines in waitlist removal among prevalent patients and similarly a decline in waitlisting and transplants in incident ESRD patients in March 2020 through May 2020 compared to prior years. We also observed that trends generally returned to normal starting in June and July 2020 and reflected data similar to prior years. However, we also indicated that we would continue to monitor and review the data and would consider proposing in a future rulemaking to suppress one or more individual ESRD QIP measures for a future ESRD QIP payment year if we conclude that circumstances caused by the COVID–19 PHE have affected those measures and the resulting TPSs based on CY 2021 data.

After reviewing data for the PPPW clinical measure for CY 2021, we believe that circumstances caused by the COVID–19 PHE have affected our ability to make reliable national, side-by-side comparisons of facility performance on the PPPW measure. Recent analyses indicate that measure performance has declined over the course of the COVID–19 PHE. Although the initial disruptions in care and associated effects on the PPPW measure at the beginning of the COVID–19 PHE initially stabilized, we have since observed a continuous decrease in the levels of PPPW clinical measure performance. We believe this decrease is indicative overall of the significant impact of the COVID–19 PHE on the measure. For example, in January 2019, the monthly PPPW rate was 19 percent. By contrast, the monthly PPPW rate for December 2021 was 16.9 percent, which we believe reflects a significant deviation in national performance on the measure. We have also observed that a greater number of facilities would receive lower scores in PY 2023 as compared to PY 2022, reflecting poorer performance overall on the measure. For example, our simulations indicate that the percentage of facilities receiving scores lower than 5 (out of 10; a higher score reflects better performance) have increased at almost every data point. Notably, the percentage of facilities estimated to receive a score of 0, 1, or 2 increased the most between the PY 2022 and PY 2023, indicating that facilities are more likely to receive a lower score in PY 2023. Moreover, the percentage of facilities receiving scores higher than 5 on the PPPW clinical measure in PY 2023 have decreased at each data point. Given the correlation between decreasing scores and the pandemic's impact on care delivery and patient ability to access the appropriate level of care in light of COVID–19 precautions, we believe that the COVID–19 PHE continues to have a significant impact on the PPPW clinical measure during CY 2021.

Our analysis of the available data indicates that the COVID–19 PHE has had significant effects on the PPPW clinical measure and would result in significant deviation in national performance on the measure during the COVID–19 PHE. Not only are there effects on patients diagnosed with COVID–19, but the presence of the virus strongly affected treatment patterns of dialysis patients in CY 2020 and continued to do so in CY 2021, and we are concerned that similar effects would be seen in the balance of the 2021 calendar year as the PHE had continued. Because the Delta variant and the Omicron variant surged through geographic regions of the country unevenly, we are concerned that facilities in different regions of the country would have been affected differently throughout the 2021 year, thereby skewing measure performance and affecting national comparability due to significant and unprecedented changes in patient case volumes or facility-level case mix. Given the limitations of the data available to us for CY 2021, we believe the resulting performance measurement on the PPPW clinical measure would not be sufficiently reliable or valid for use in the ESRD QIP for scoring and payment adjustment purposes.

We believe that the PPPW clinical measure is an important part of the ESRD QIP measure set. However, we are concerned that the ongoing COVID–19 PHE has affected measure performance

[223] Bloomberg, U.S. Hospital Staff Shortages Hit Most in a Year on Covid Surge, *https://www.bloomberg.com/news/articles/2022-01-05/one-in-five-u-s-hospitals-face-staffing-shortages-most-in-year* (citing HHS data).

[224] Fresenius Medical Care Press Release, Statement regarding COVID–19 related supply and staff shortages. Available at: *https://fmcna.com/company/covid-19-resource-center/*.

on the current PPPW clinical measure such that we would not be able to score facilities fairly or equitably on it. Additionally, we would continue to collect the measure's data from participating facilities so that we could monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We would also continue to provide confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We also intend to publicly report PY 2023 data where feasible and appropriately caveated.

We are currently exploring ways to adjust effectively for the systematic effects of the COVID–19 PHE on the PPPW clinical measure. However, we are still working to improve these COVID–19 adjustments and verify the validity of a potential modified version of the PPPW clinical measure as additional data become available. As an alternative, we considered whether we could exclude patients with a diagnosis of COVID–19 from the PPPW clinical measure cohort, but we determined suppression would provide additional time and months of data for us to more thoroughly evaluate a broader range of alternatives. We want to ensure that the measure reflects care provided to ESRD patients and we are concerned that excluding otherwise eligible patients may not accurately reflect the care provided, particularly given the unequal distribution of COVID–19 patients across facilities over time.

We welcome public comment on our proposal to suppress the PPPW clinical measure for PY 2023.

g. Proposal To Suppress the Kt/V Dialysis Adequacy Clinical Measure for PY 2023

In this proposed rule, we are proposing to suppress the Kt/V Dialysis Adequacy clinical measure for PY 2023 program year under Measure Suppression Factor 1, Significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly better or significantly worse as compared to historical performance during the immediately preceding program years. We refer readers to the CY 2022 ESRD PPS final rule for previous analysis on the overall impact of the COVID–19 PHE on ESRD quality measure performance (86 FR 61910 through 61913).

The Kt/V Dialysis Adequacy clinical measure is the percentage of all patient months for patients whose delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period. The Kt/V Dialysis Adequacy clinical measure is defined as a measure of dialysis sufficiency where *K* is dialyzer clearance, *t* is dialysis time, and *V* is total body water volume. The measure evaluates the success of achieving the delivered dialysis dose. The intent of the Kt/V measure is to improve health care delivery by providing facilities with evidence-based parameters for optimizing ESRD patient outcomes over time.

In the CY 2022 ESRD PPS final rule (86 FR 61910), several commenters recommended that CMS suppress the Kt/V Dialysis Adequacy clinical measure, noting that the COVID–19 PHE had a significant impact on catheter rates, which has a corresponding impact on the Kt/V measure, as patients with catheters will have lower Kt/V rates. One commenter also noted the Kt/V Dialysis Adequacy clinical measure should be suppressed under Suppression Factor 1, due to significant deviation in national measure performance. At the time, we responded there was not sufficient data to determine whether suppression was appropriate for the Kt/V Dialysis Adequacy clinical measure. Although performance on the Kt/V Dialysis Adequacy clinical measure deviated temporarily, our analysis indicated that Kt/V rates stabilized shortly thereafter and reflected measure performance similar to prior years. Based on our analysis at the time, Kt/V rates in CY 2020 were similar to rates in CY 2019 until April where they dropped by an average of 0.4 percent. However, beginning in June 2020, Kt/V rates were the same as or higher than national average rates in March 2020.

After reviewing data for the Kt/V Dialysis Adequacy clinical measure for CY 2020 and CY 2021, we believe that circumstances caused by the COVID–19 PHE have affected the measure and the resulting TPS. Although the initial disruptions of care at the beginning of the COVID–19 PHE, associated with multiple transient changes to factors that contribute to dialysis adequacy (Kt/V), were temporary, we have observed continued deviations in Kt/V clinical measure performance over the past 2 years and we believe that this is indicative of the significant impact of the COVID–19 PHE on the measure. Notably, delays in hemodialysis treatment, due to COVID–19 infection or logistical challenges with care delivery, exacerbated ESRD sequelae including hyperkalemia, uremic encephalopathy, and fluid volume overload.[225] The confluence of these factors likely contributed to declines in Kt/V clinical measure performance.

Our simulations comparing PY 2022 scoring distributions with estimated PY 2023 scoring distributions show that the percentage of facilities receiving scores less than 7 (out of 10; a higher score reflects better performance) have increased at almost every data point, whereas the percentage of facilities receiving scores higher than 7 have decreased at almost every data point. The percentage of facilities receiving a score of score of 0, 1, 2, 3, or 4 increased the most between the 2 years, indicating that facilities are more likely to receive a lower score in PY 2023. Given the correlation between decreasing scores and the pandemic's impact on care delivery and patient ability to access the appropriate level of care in light of COVID–19 precautions,[226] we believe that the COVID–19 PHE continued to have a significant impact on the Kt/V clinical measure during CY 2021.

Our analysis of the available data indicates that the COVID–19 PHE has had significant effects on the Kt/V Dialysis Adequacy clinical measure for ESRD patients and would result in significant deviation in national performance on the measure during the COVID–19 PHE, which could be significantly worse as compared to historical performance during the immediately preceding program years. Because the Delta variant and Omicron variant surged through geographic regions of the country unevenly, we are concerned that facilities in different regions of the country have been affected differently throughout the 2021 calendar year, resulting in skewing of measure performance and affecting national comparability due to significant and unprecedented changes in patient case volumes or facility-level case mix. We note that our scoring simulations indicate that a high percentage of facilities would receive a score of zero for PY 2023. Given the limitation of the data available to us for CY 2021, we believe the resulting performance measurement of the Kt/V Dialysis Adequacy clinical measure would not be sufficiently reliable or valid for use in the ESRD QIP for

[225] Connerney, M., Sattar, Y., Rauf, H., Mamtani, S., Ullah, W., Michaelson, N., Dhamrah, U., Lal, N., Latchana, S., & Stern, A.S. (2021). Delayed hemodialysis in COVID–19: Case series with literature review. *Clinical nephrology. Case studies, 9*, 26–32. *https://doi.org/10.5414/CNCS110240.*

[226] National Kidney Foundation, *COVID–19 and its Impact on Kidney Patients Utilizing U.S. Dialysis Centers* (Jan. 18, 2022), *https://www.kidney.org/news/covid-19-and-its-impact-kidney-patients-utilizing-u-s-dialysis-centers.*

scoring and payment adjustment purposes.

We believe that the Kt/V Dialysis Adequacy clinical measure is an important part of the ESRD QIP measure set. However, we are concerned that the ongoing COVID–19 PHE has affected measure performance on the current Kt/V Dialysis Adequacy clinical measure such that we would not be able to score facilities fairly or equitably on it. Moreover, we would continue to collect the measure's data from participating facilities so that we could monitor the effect of the COVID–19 PHE circumstances on quality measurement and determine the appropriate policies in the future. We would also continue to provide confidential feedback reports to facilities as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We also intend to publicly report PY 2023 data where feasible and appropriately caveated.

We are currently exploring ways to adjust effectively for the systematic effects of the COVID–19 PHE on the Kt/V Dialysis Adequacy clinical measure. However, we are still working to improve these COVID–19 adjustments and verify the validity of a potential modified version of the Kt/V Dialysis Adequacy clinical measure as additional data become available.

We welcome public comment on our proposal to suppress the Kt/V Dialysis Adequacy clinical measure for PY 2023.

3. Technical Measure Specification Updates To Include a Covariate Adjustment for COVID–19 for the SHR and SRR Measures Beginning With PY 2025

In the CY 2013 ESRD PPS final rule, we finalized a subregulatory process to incorporate technical measure specification updates into the measure specifications we have adopted for the ESRD QIP (77 FR 67475 through 67477).

As we continue to evaluate the effects of COVID–19 on the ESRD QIP measure set, we have observed both short-term effects on both hospital admissions and readmissions. In addition, for some patients COVID–19 continues to have lasting effects, including but not limited to fatigue, cough, palpitations, and others potentially related to organ damage, post viral syndrome, and post-critical care syndrome.[227] These clinical conditions could affect a patient's risk of complications following an index admission or readmission and, as a result, impact a facility's performance on the SHR clinical measure or the SRR clinical measure. In order to account for case mix among facilities, the current risk adjustment approach for these measures include covariates for clinical comorbidities that are relevant and have relationships with the outcome, for example patient history of diabetes or obesity. Therefore, in order to adequately account for patient case mix, we are further modifying the technical measure specifications for the SHR and SRR measures to include a covariate adjustment for patient history of COVID–19. We believe these changes are technical in nature because they do not substantively change the measures themselves and, therefore, are not required to be implemented through rulemaking.

This inclusion of the covariate adjustment for patient history of COVID–19 would be effective beginning with the PY 2025 program year for the SHR clinical measure and the SRR clinical measure, and we would also apply this adjustment for purposes of calculating the performance standards for that program year. As discussed in section IV.E.1.b, we are proposing to convert the STrR reporting measure to a clinical measure beginning with PY 2025. We are also considering whether it would be appropriate to add a covariate adjustment for patient history of COVID–19 to the STrR clinical measure, beginning with PY 2025, and will announce that technical update, if appropriate, at a later date.

For more information on the application of covariate adjustments, including the technical updates we are announcing in this proposed rule, please see the Technical Specifications for ESRD QIP Measures (available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications*) and the CMS ESRD Measures Manual (available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/06_MeasuringQuality*).

C. Proposed Updates to the Performance Standards Applicable to the PY 2023 Clinical Measures

Our current policy is to automatically adopt a performance and baseline period for each year that is 1 year advanced from those specified for the previous payment year (84 FR 60728). Under this policy, CY 2021 is currently the performance period and CY 2020 is the baseline period for the PY 2023 ESRD QIP. However, under the nationwide ECE that we granted in response to the COVID–19 PHE, first and second quarter data for CY 2020 are excluded from scoring for purposes of the ESRD QIP (85 FR 54829 through 54830). Accordingly, in the CY 2022 ESRD PPS final rule (86 FR 61922 through 61923), for PY 2024, we finalized calculating performance standards using CY 2019 data due to concerns about using partial year data (86 FR 61922 through 61923). Similarly, we are concerned that it would be difficult to assess performance standards for PY 2023 based on partial year data. Our preliminary analysis indicates that the effect of the excluded data could create inflated performance standards for PY 2023 and we would potentially be required to use these for future payment years due to the requirement that the prior year's standard cannot be higher than the current year's standard. This may skew achievement and improvement thresholds for facilities and therefore may result in performance standards that do not accurately reflect levels of achievement and improvement.

Our current policy substitutes the performance standard, achievement threshold, and/or benchmark for a measure for a performance year if final numerical values for the performance standard, achievement threshold, and/or benchmark are worse than the numerical values for that measure in the previous year of the ESRD QIP (82 FR 50764). We adopted this policy because we believe that the ESRD QIP should not have lower performance standards than in previous years and therefore, adopted flexibility to substitute the performance standard, achievement threshold, and benchmark in appropriate cases.

Although the lower performance standards would be substituted with those from the prior year, the higher performance standards would be used to set performance standards for certain measures, even though they would be based on partial year data. We continue to be concerned that this may create performance standards for certain measures that would be difficult for facilities to attain with 12 months of data.

Therefore, we are proposing to calculate the performance standards for PY 2023 using CY 2019 data, which are the most recently available full calendar year of data we can use to calculate those standards. Due to the impact of CY 2020 data that are excluded from the ESRD QIP for scoring purposes, we believe that using CY 2019 data for performance standard setting purposes is appropriate. We are also proposing to amend 413.178(d)(2) to reflect both our

[227] Raveendran, A.V., Jayadevan, R. and Sashidharan, S., *Long COVID: An overview.* Available at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8056514/.* Accessed on December 15, 2021.

proposed updates applicable to the PY 2023 performance standards, as well as our previously finalized update to the PY 2024 performance standards.

We welcome public comments on this proposal.

D. Technical Updates to the SRR and SHR Clinical Measures Beginning With the PY 2024 ESRD QIP

In the CY 2017 ESRD PPS final rule, we adopted the SHR clinical measure under the authority of section 1881(h)(2)(B)(ii) of the Act (81 FR 77906 through 77911). The SHR clinical measure is a National Quality Forum (NQF)-endorsed all-cause, risk-standardized rate of hospitalizations during a 1-year observation window. The standardized hospitalization ratio is defined as the ratio of the number of hospital admissions that occur for Medicare ESRD dialysis patients treated at a particular facility to the number of hospitalizations that would be expected given the characteristics of the facility's patients and the national mean for facilities. In the CY 2015 ESRD PPS final rule, we adopted the SRR clinical measure under the authority of section 1881(h)(2)(B)(ii) of the Act (79 FR 66174 through 66182). The standardized readmission ratio is defined as the ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day hospital readmissions. Both the SHR clinical measure and the SRR clinical measure are calculated as a ratio, but can also be expressed as a rate.

Hospitalization and readmission rates vary across facilities even after adjustment for patient characteristics, suggesting that hospitalizations and readmissions might be influenced by facility practices. Both an adjusted facility-level standardized hospitalization ratio and an adjusted facility-level standardized readmissions ratio, accounting for differences in patients' characteristics, play an important role in identifying potential quality issues, and help facilities provide cost-effective quality health care to help reduce admissions or readmissions to the hospital for dialysis patients as well as limit escalating medical costs. We have weighted scoring of the SHR clinical measure and the SRR clinical measure to reflect the importance of the measures on the quality of patient care. In the CY 2019 ESRD PPS final rule, the SHR clinical measure and the SRR clinical measure each accounted for 14 percent of the TPS (83 FR 56992). In CY 2019, with average weights of more than 15 percent (after reweighting of missing measures), the SHR clinical measure and the SRR clinical measure were the two measures with the largest weight in calculating the TPS for each facility.

In the CY 2013 ESRD PPS final rule, we finalized a subregulatory process to incorporate technical measure specification updates into the measure specifications we have adopted for the ESRD QIP (77 FR 67475 through 67477). We are updating the technical specifications to revise how we express the results of the SHR clinical measure and the SRR clinical measure so that those results are expressed as a Risk-Standardized Hospitalization Rate (RSHR) and a Risk-Standardized Readmission Rate (RSRR), respectively. Stakeholders have previously expressed concern that the SHR clinical measure and the SRR clinical measure are difficult to interpret and track facility performance over time when expressed as ratios, and have recommended expressing those ratios as rates when scoring. Although there are widespread national improvements in hospitalization rates and readmission rates, individual facilities may not their own improvement reflected if their measure results are reflected as ratios because SHR and SRR measures effectively standardize the ratios to 1.0 each calendar year and all facilities' ratios are calculated using national-level performance in each calendar year. Another concern stakeholders have raised is that the ratios are difficult to understand and to determine how to use these ratios for quality improvement efforts.

In light of these concerns, we are updating the technical specifications to change the scoring methodology for the SRR clinical measure and the SHR clinical measure such that a facility's results are expressed as a rate in the performance period that is compared directly to its rate in the baseline period. In response to public comments indicating a perception that overall facility performance on ESRD QIP measures was recently improving as payment reductions were increasing, we assessed trends in facility performance through 2019 to examine facility performance on the SHR clinical measure and the SRR clinical measure over time. We also calculated the RSHR and the RSRR. We calculated the RSHR by multiplying SHR by the national observed hospitalization rate (per patient-year at risk) in the calendar year. Similarly, we multiplied the SRR by the national observed readmission rate (per index discharge) in the calendar year to determine the RSRR. Both ESRD QIP and Dialysis Facility Reports (DFR) data were used in these analyses. Data from ESRD QIP were available from CYs 2018 to 2019 for the SRR clinical measure and from CYs 2015 to 2019 for the SHR clinical measure. Additionally, we used data from the publicly available DFRs from CYs 2010 to 2018 for the SHR clinical measure and from CYs 2014 to 2018 for the SRR clinical measure to compare to the ESRD QIP calculations.

We believe these changes are technical in nature because they do not substantively change the measures themselves and, therefore, are not required to be implemented through rulemaking. Our analysis found that expressing the measure performance as a rate instead of a ratio would communicate the same information in a clearer way. After the SHR clinical measure and the SRR clinical measure were added to the ESRD QIP measure set, that SHR and SRR distributions were similar from year to year. Median SHR has consistently remained below 1.0, while median SRR has remained around 1.0 each year. RSHR and RSRR have remained stable since then as well. These trends show that as ESRD QIP payment reductions were increasing from PY 2018 to PY 2020 (corresponding to CY 2016 to CY 2018 facility performance for most measures), we do not find evidence of overall declines in risk-adjusted hospitalization and readmission rates. Furthermore, in recent years, the national readmission or hospitalization rates have been relatively stable or slightly increasing. Therefore, revising how we express SHR or SRR measure results to be expressed as RSHR or RSRR, respectively, each year would not result in higher ESRD QIP scores.

Our analysis found that expressing the SHR clinical measure and SRR clinical measure results as rates would reflect the same level of measure performance as expressing those results as ratios, and we believe that expressing the measure results rates would help providers and patients better understand a facility's performance on the measures, and would be more intuitive for a facility to track its performance from year to year.

Further, this technical update would also more closely align with the measure result calculation methodology for the ESRD QIP with that used in the Dialysis Facility Compare Star Ratings Program. For star ratings calculations, an adjustment factor is applied for the standardized ratio measures, accounting for differences in population event rates between the baseline period and evaluation period data, so that an adjusted evaluation period ratio (a proxy for rate converted from ratio) value reflects the same value it would

have in the baseline period.[228] We provide the currently finalized performance standards for the PY 2024 SHR and SRR clinical measures in Table 16, and the revised PY 2024 performances standards for the updated SHR and SRR clinical measures in Table 17.

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TABLE 16: Current Performance Standards for the PY 2024 ESRD QIP SHR and SRR Clinical Measures Using the Most Recently Available Data

Measure	Achievement Threshold (15th Percentile of National Performance)	Median (50th Percentile of National Performance)	Benchmark (90th Percentile of National Performance)
Standardized Readmission Ratio	1.268*	0.998*	0.629*
Standardized Hospitalization Ratio	1.230	0.971	0.691
*Values are also the final performance standards for those measures for PY 2023. In accordance with our longstanding policy, we are using those numerical values for those measures for PY 2024 because they are higher standards than the PY 2024 numerical values for those measures.			

Data sources: VAT measures: 2019 CROWNWeb; SRR, SHR: 2019 Medicare claims; Kt/V: 2019 CROWNWeb; Hypercalcemia: 2019 CROWNWeb; NHSN: 2019 CDC; ICH CAHPS: CMS 2019; PPPW: 2019 CROWNWeb and 2019 OPTN.

TABLE 17: Numerical Values for the Performance Standards for the Updated PY 2024 ESRD QIP SHR and SRR Clinical Measures, Expressed as Rates, Using the Most Recently Available Data

Measure	Achievement Threshold (15th Percentile of National Performance)	Median (50th Percentile of National Performance)	Benchmark (90th Percentile of National Performance)
Standardized Readmission Ratio[a]	34.27	26.97	17.02
Standardized Hospitalization Ratio[b]	187.80	148.33	105.54

[a]Rate calculated as a percentage of hospital discharges

[b]Rate per 100 patient-years

Data sources: VAT measures: 2019 CROWNWeb; SRR, SHR, STrR: 2019 Medicare claims; Kt/V: 2019 CROWNWeb; Hypercalcemia: 2019 CROWNWeb; NHSN: 2019 CDC; ICH CAHPS: CMS 2019; PPPW: 2019 CROWNWeb and 2019 OPTN.

We welcome public comments on this technical update.

E. Proposed Updates to Requirements Beginning With the PY 2025 ESRD QIP

1. PY 2025 ESRD QIP Measure Set

Under our current policy, we retain all ESRD QIP measures from year to year unless we propose through rulemaking to remove them or otherwise provide notification of immediate removal if a measure raises potential safety issues (77 FR 67475). Accordingly, the PY 2025 ESRD QIP measure set would include the same 14 measures as the PY 2024 ESRD QIP measure set (85 FR 71465 through 71466). In section IV.E.1.a of this proposed rule, we are also proposing to adopt a COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) reporting measure beginning in PY 2025. In section IV.E.1.b of this proposed rule, we are proposing to convert the STrR reporting measure to a clinical measure beginning in PY 2025, and in section IV.E.1.c, we are proposing to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025. These measures are described in Table 18 in this proposed rule. For the most recent information on each measure's technical specifications for PY 2025, we refer readers to the CMS ESRD Measures Manual for the 2022 Performance Period.[229]

[228] The University of Michigan Kidney Epidemiology and Cost Center. (2018). Technical Notes on the Dialysis Facility Compare Quality of Patient Care Star Rating Methodology for the October 2018 Release. Available at: *https://dialysisdata.org/sites/default/files/content/Methodology/Updated_DFC_Star_Rating_Methodology_for_October_2018_Release.pdf.*

[229] *https://www.cms.gov/files/document/esrd-measures-manual-v70.pdf.*

TABLE 18: Proposed PY 2025 ESRD QIP Measure Set

National Quality Forum (NQF) #	Measure Title and Description
0258	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure Measure assesses patients' self-reported experience of care through percentage of patient responses to multiple testing tools.
2496	Standardized Readmission Ratio (SRR), a clinical measure* Ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day readmissions.
Based on NQF #2979	Standardized Transfusion Ratio (STrR), a reporting measure** Ratio of the number of observed eligible red blood cell transfusion events occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected.
N/A	(Kt/V) Dialysis Adequacy Comprehensive, a clinical measure A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume. Percentage of all patient months for patients whose delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.
2977	Hemodialysis Vascular Access: Standardized Fistula Rate clinical measure Measures the use of an arteriovenous (AV) fistula as the sole means of vascular access as of the last hemodialysis treatment session of the month.
2978	Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure Measures the use of a catheter continuously for 3 months or longer as of the last hemodialysis treatment session of the month.
1454	Hypercalcemia, a clinical measure*** Proportion of patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL.
1463	Standardized Hospitalization Ratio (SHR), a clinical measure* Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.
Based on NQF #0418	Clinical Depression Screening and Follow-Up, a reporting measure Facility reports in End Stage Renal Disease Quality Reporting System (EQRS) one of six conditions for each qualifying patient treated during performance period.
N/A	Ultrafiltration Rate (UFR), a reporting measure Number of patient-months for which a facility reports elements required for ultrafiltration rates for each qualifying patient.
Based on NQF #1460	National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients, a clinical measure The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.
N/A	NHSN Dialysis Event reporting measure Number of months for which facility reports NHSN Dialysis Event data to the Centers for Disease Control and Prevention (CDC).
N/A	Percentage of Prevalent Patients Waitlisted (PPPW), a clinical measure Percentage of patients at each facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period.
2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec), a reporting measure Percentage of patient-months for which medication reconciliation was performed and documented by an eligible professional.
N/A	COVID-19 Healthcare Personnel (HCP) Vaccination, a reporting measure**** Percentage of HCP who receive a complete COVID-19 vaccination course.

* We are updating the SHR clinical measure and the SRR clinical measure to be expressed as risk-standardized rates beginning in PY 2024, as discussed in section IV.D of this proposed rule.

**We are proposing to convert the STrR reporting measure to a clinical measure beginning in PY 2025, as discussed in section IV.E.1.b of this proposed rule.

***We are proposing to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025, as discussed in section IV.E.1.c of this proposed rule.

****We are proposing to adopt the COVID-19 HCP Vaccination measure beginning in PY 2025, as discussed in section IV.E.1.a of this proposed rule.

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We discuss our proposal to adopt the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) reporting measure, our proposal to convert the

STrR reporting measure to a clinical measure, and our proposal to convert the Hypercalcemia clinical measure to a reporting measure in the following sections.

a. Proposal To Adopt the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Reporting Measure Beginning With the PY 2025 ESRD QIP

(1) Background

On January 31, 2020, the Secretary declared a PHE for the U.S. in response to the global outbreak of SARS–CoV–2, a novel (new) coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[230] COVID–19 is a contagious respiratory infection [231] that can cause serious illness and death. Older individuals and those with underlying medical conditions are considered to be at higher risk for more serious complications from COVID–19.[232]

COVID–19 has had significant negative health effects—on individuals, communities, and the nation as a whole. Consequences for individuals who have COVID–19 include morbidity, hospitalization, mortality, and post-COVID conditions (also known as long COVID). As of March 16, 2022, over 79 million COVID–19 cases, over 4.5 million new COVID–19 related hospitalizations, and almost 965,000 COVID–19 deaths have been reported in the U.S.[233]

The CDC has confirmed that the three main ways that COVID–19 is spread are: (1) Breathing in air when close to an infected person who is exhaling small droplets and particles that contain the virus; (2) Having these small droplets and particles that contain virus land on the eyes, nose, or mouth, especially through splashes and sprays like a cough or sneeze; and (3) Touching eyes, nose, or mouth with hands that have the virus on them.[234] According to the CDC, those at greatest risk of infection are persons who have had prolonged, unprotected close contact (that is, within 6 feet for 15 minutes or longer) with an individual with confirmed SARS–CoV–2 infection, regardless of whether the individual has symptoms.[235] Although personal protective equipment (PPE) and other infection-control precautions can reduce the likelihood of transmission in health care settings, COVID–19 can spread between healthcare personnel (HCP) and patients, or from patient to patient, given the close contact that may occur during the provision of care.[236] The CDC has emphasized that health care settings can be high-risk places for COVID–19 exposure and transmission.[237]

Vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19 and ultimately help restore societal functioning.[238] On December 11, 2020, FDA issued the first Emergency Use Authorization (EUA) for a COVID–19 vaccine in the U.S.[239] Subsequently, FDA issued EUAs for additional COVID–19 vaccines [240] and, after a rigorous review process, granted approval to two vaccines.[241]

We believe that it is important to incentivize and track HCP vaccination for COVID–19 in facilities through quality measurement in order to protect health care workers, patients, and caregivers, and to help sustain the ability of these facilities to continue serving their communities throughout the PHE and beyond. We recognize the importance of COVID–19 vaccination, and have finalized proposals to include a COVID–19 HCP vaccination measure in quality reporting programs for other care settings, such as the Inpatient Psychiatric Facility Quality Reporting Program (86 FR 42633 through 42640), the Hospital Inpatient Quality Reporting Program (86 FR 45374 through 45382), the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program (86 FR 45428 through 45434), the Long-Term Care Hospital Quality Reporting Program (LTCH QRP) (86 FR 45438 through 45446), the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP) (86 FR 42385 through 42396), and the Skilled Nursing Facility Quality Reporting Program (86 FR 42480 through 42489).

HCP are at risk of carrying COVID–19 infection to patients, experiencing illness or death themselves as a result of contracting COVID–19, and transmitting COVID–19 to their families, friends, and the general public. For further information regarding the importance of vaccination among HCP, we refer readers to the ''Omnibus COVID–19 Health Care Staff Vaccination,'' an interim final rule with comment that was issued on November, 11, 2021, requiring COVID–19 vaccination of eligible staff at health care facilities that participate in the Medicare and Medicaid programs (such as facilities participating in ESRD QIP) (86 FR 61556 through 615560). We believe that facilities should track the level of vaccination among their HCP as part of their efforts to assess and reduce the risk of transmission of COVID–19 within their facilities. HCP vaccination can potentially reduce illness that leads to work absence and limit disruptions to care.[242] Data from influenza vaccination demonstrates that provider uptake of the vaccine is associated with that provider recommending vaccination to patients,[243] and we believe that HCP COVID–19 vaccination in facilities could similarly increase uptake among that patient population. We also believe

[230] U.S. Dept of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2020). Determination that a Public Health Emergency Exists. Available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[231] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.*

[232] Ibid.

[233] *https://covid.cdc.gov/covid-data-tracker#datatracker-home.*

[234] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on July 15, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[235] Centers for Disease Control and Prevention. (2021). When to Quarantine. Accessed on April 2, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html.*

[236] Centers for Disease Control and Prevention. (2021). Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID–19. Accessed on April 2 at: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Transmission.*

[237] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb Mortal Wkly Rep. 2020; 69(49): 1857–1859. Available at: *https://www.cdc.gov/mmwr/volumes/69/wr/mm6949e1.htm.*

[238] Centers for Disease Control and Prevention. (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed on April 3, 2021 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.*

[239] U.S. Food and Drug Administration. (2020). Pfizer-BioNTech COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/150386/download.* (as reissued on September 22, 2021).

[240] U.S. Food and Drug Administration. (2020). Moderna COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144636/download* (as reissued on August 12, 2021); U.S. Food and Drug Administration. (2021). Janssen COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download* (as reissued on June 10, 2021).

[241] FDA Approves First COVID–19 Vaccine, Available at *https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.* Spikevax and Moderna COVID–19 Vaccine, Available at: *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/spikevax-and-moderna-covid-19-vaccine.*

[242] Centers for Disease Control and Prevention. Overview of Influenza Vaccination among Health Care Personnel. October 2020. (2020) Accessed March 16, 2021 at: *https://www.cdc.gov/flu/toolkit/long-term-care/why.htm.*

[243] Measure Applications Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

that publishing the HCP vaccination rates would be helpful to many patients, including those who are at high-risk for developing serious complications from COVID–19 such as dialysis patients, as they choose facilities from which to seek treatment. Patients undergoing hemodialysis face greater risk for adverse health outcomes if they contract COVID–19 and during the Delta and Omicron surges of 2021, increases in case rates were directly proportionate to vaccination rates at the county level across the United States [244] [245] Under CMS' Meaningful Measures Framework, the COVID–19 HCP Vaccination measure would address the quality priority of ''Promoting Effective Prevention and Treatment of Chronic Disease'' through the Meaningful Measures Area of ''Preventive Care.''

(2) Overview of Measure

The COVID–19 HCP Vaccination measure is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCP in non-long-term care facilities such as ESRD facilities.

The denominator is the number of HCP eligible to work in the ESRD facility for at least one day during the reporting period (as described in section IV.E.1.a.(5)) excluding persons with contraindications to COVID–19 vaccination that are described by the CDC.[246] [247]

The numerator is the cumulative number of HCP eligible to work in the ESRD facility for at least one day during the reporting period (as described in section IV.E.1.a.(5)) and who received a complete vaccination course against COVID–19 using an FDA-authorized or approved vaccine for COVID–19. A complete vaccination course is defined under the specific FDA EUA or approval and may require multiple doses or regular revaccination.[248] [249] Vaccination coverage is defined, for purposes of this measure, as the percentage of HCP eligible to work at the facility for at least 1 day who received a complete vaccination course against COVID–19. The specifications for this measure are available at *https://www.cdc.gov/nhsn/nqf/index.html.*

(3) Review by the Measure Applications Partnership

The COVID–19 HCP Vaccination measure was included on the publicly available ''List of Measures under Consideration for December 21, 2020'' (MUC List), a list of measures under consideration for use in various Medicare programs.[250] When the Measure Applications Partnership (MAP) Hospital Workgroup convened on January 11, 2021, it reviewed measures on the MUC List including the COVID–19 HCP Vaccination measure. The MAP Hospital Workgroup recognized that the proposed measure represents a promising effort to advance measurement for an ongoing and evolving national pandemic and that it would bring value to the ESRD QIP measure set by providing transparency about an important COVID–19 intervention to help prevent infections in HCP and patients.[251] The MAP Hospital Workgroup also stated that collecting information on COVID–19 vaccination coverage among HCP, and providing feedback to facilities, would allow facilities to benchmark coverage rates and improve coverage in their facility. The MAP Hospital Workgroup further noted that reducing rates of COVID–19 in HCP may reduce transmission among a patient population that is highly susceptible to illness and disease, and also reduce instances of staff shortages due to illness.[252]

In its preliminary recommendations, the MAP Hospital Workgroup did not support this measure for rulemaking, subject to potential for mitigation.[253] To mitigate its concerns, the MAP Hospital Workgroup believed that the measure needed well-documented evidence, finalized specifications, testing, and NQF endorsement prior to implementation.[254] Subsequently, the MAP Coordinating Committee reviewed the COVID–19 HCP Vaccination measure and the preliminary recommendation of the Hospital Workgroup, and decided to recommend conditional support for rulemaking contingent on CMS bringing the measure back to the MAP once the specifications were further refined.[255] In its final report, the MAP further noted that the measure would add value to the ESRD QIP measure set by providing visibility into an important intervention to limit COVID–19 infections in HCP and the ESRD patients for whom they provide care.[256]

In response to the MAP's request that CMS return with the measure once the specifications are further refined, we met with the MAP Coordinating Committee accompanied by the CDC on March 15, 2021 to address vaccine availability, the alignment of the COVID–19 HCP Vaccination measure as closely as possible with the Influenza HCP vaccination measure (NQF #0431) specifications, and the definition of HCP used in the measure. At this meeting, with the CDC, we also presented preliminary findings from ongoing testing of the numerator of COVID–19 HCP Vaccination measure, which showed that the numerator data should be feasible and reliable.[257] Testing of the numerator, the number of HCP vaccinated, involved a comparison of vaccination data reported to the CDC by long-term care facilities (LTCFs) through the CDC's National Healthcare Safety Network (NHSN) with data reported to the CDC through the federal pharmacy partnership program for delivering vaccination to LTC facilities. These two data collection systems are independent but show high correlation. In initial analyses of the first month of

[244] Cuadros DF, Miller FD, Awad S, Coule P, MacKinnon NJ. Analysis of Vaccination Rates and New COVID–19 Infections by US County, July–August 2021. *JAMA Netw Open.* 2022;5(2):e2147915. doi:10.1001/jamanetworkopen.2021.47915.

[245] Iuliano AD, Brunkard JM, Boehmer TK, et al. Trends in Disease Severity and Health Care Utilization During the Early Omicron Variant Period Compared with Previous SARS–CoV–2 High Transmission Periods—United States, December 2020–January 2022. MMWR Morb Mortal Wkly Rep 2022;71:146–152. DOI: *http://dx.doi.org/10.15585/mmwr.mm7104e4external* icon.

[246] Centers for Disease Control and Prevention. Contraindications and precautions. (2021) Accessed January 7, 2022 at: *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications.*

[247] Centers for Disease Control and Prevention. Measure Specification: NHSN COVID–19 Vaccination Coverage Updated August 2021. (2021) Accessed March 29, 2022 at: *https://www.cdc.gov/nhsn/pdfs/nqf/covid-vax-hcpcoverage-508.pdf.*

[248] Measure Applications Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[249] Centers for Disease Control and Prevention. Measure Specification: NHSN COVID–19 Vaccination Coverage Updated August 2021. (2021) Accessed March 29, 2022 at: *https://www.cdc.gov/nhsn/pdfs/nqf/covid-vax-hcpcoverage-508.pdf.*

[250] National Quality Forum. List of Measures Under Consideration for December 21, 2020. Accessed at: *https://www.cms.gov/files/document/measures-under-consideration-list-2020-report.pdf* on January 29 2021.

[251] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[252] Ibid.

[253] Ibid.

[254] Ibid.

[255] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 23, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[256] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 23, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[257] For more information on testing results and other measure updates, please see the Meeting Materials (including Agenda, Recording, Presentation Slides, Summary, and Transcript) of the March 15, 2021 meeting available at *https://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367.*

vaccination from December 2020 to January 2021, the number of HCP vaccinated in approximately 1,200 facilities was highly correlated between these two systems with a correlation coefficient of nearly 90 percent in the second two weeks of reporting.[258] Because of the high correlation across a large number of facilities, including ESRD facilities, and the high number of HCP within those facilities receiving at least one dose of the COVID–19 vaccine, we believe these data indicate the measure is feasible and reliable for use in the ESRD QIP.

(4) NQF Endorsement

Section 1881(h)(2)(B)(i) of the Act states that subject to subparagraph (ii), any measure specified by the Secretary for the ESRD QIP must have been endorsed by the entity with a contract under section 1890(a) of the Act. The National Quality Forum (NQF) currently holds this contract. Under section 1881(h)(2)(B)(ii) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

The proposed COVID–19 HCP Vaccination measure is not NQF endorsed. The CDC, in collaboration with CMS, submitted the measure for consideration in the NQF Fall 2021 measure cycle.

Because this measure is not NQF-endorsed, we considered whether there are other available measures that assess COVID–19 vaccination rates among HCP. We found no other feasible and practical measures on the topic of COVID–19 vaccination among HCP, therefore the exception in section 1881(h)(2)(B)(ii) of the Act applies. We believe it is important to propose this measure as quickly as feasible to address the ongoing COVID–19 pandemic and to prepare for potential future waves of COVID–19 variants, including the potential continued negative impact of COVID–19 infection on the ESRD patient population as well as HCP staffing shortages due to COVID–19 infection among staff.

(5) Data Collection, Submission, and Reporting

We are proposing quarterly reporting deadlines for the ESRD QIP and a 12-month performance period. Facilities would report the measure through the NHSN web-based surveillance system.[259] Facilities currently use the NHSN web-based system to report two ESRD QIP measures, the NHSN Bloodstream Infection (BSI) clinical measure and the NHSN Dialysis Event reporting measure.

To report this measure, we propose that facilities would collect the numerator and denominator for the COVID–19 HCP vaccination measure for at least one self-selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personal Safety (HPS) Component before the quarterly deadline to meet ESRD QIP requirements. While it would be ideal to have HCP vaccination data for every week of each month, we are mindful of the time and resources that facilities would need to report the data. Thus, in collaboration with the CDC, we determined that data from at least one week of each month would be sufficient to obtain a reliable snapshot of vaccination levels among a facility's healthcare personnel while balancing the costs of reporting. If a facility submits more than one week of data in a month, the most recent week's data would be used to calculate the measure, as we believe the most recent week's data would provide the most currently available information. For example, if first and third week data are submitted, third week data would be used. If first, second, and fourth week data are submitted, fourth week data would be used. Each quarter, we propose that the CDC would calculate a single quarterly COVID–19 HCP vaccination coverage rate for each facility, which would be calculated by taking the average of the data from the three weekly rates submitted by the facility for that quarter. We would publicly report the most recent quarterly COVID–19 HCP vaccination coverage rate as calculated by the CDC.

As described in section IV.E.1.a.(2) of this proposed rule, facilities would report the number of HCP eligible to have worked at the facility during the self-selected week that the facility reports data for in NHSN (denominator) and the number of those HCP who have received a complete course of a COVID–19 vaccination (numerator) during the same self-selected week.

We welcome public comment on our proposal to add a new measure, COVID–19 Vaccination Coverage among HCP, to the ESRD QIP measure set beginning with PY 2025.

b. Proposed Updates to the Standardized Transfusion Ratio (STrR) Reporting Measure Beginning With PY 2025

Under section 1881(h)(2)(A)(iv)(I) of the Act, the ESRD QIP has a statutory requirement to include an anemia management measure in the Program's measure set, and the STrR reporting measure currently satisfies that statutory requirement. In the CY 2015 ESRD PPS final rule (79 FR 66192 through 66197), we finalized the adoption of the STrR clinical measure to address gaps in the quality of anemia management, beginning with the PY 2018 ESRD QIP. The NQF endorsed a revised version of the STrR clinical measure in 2016, and in the CY 2018 ESRD PPS final rule (82 FR 50771 through 50774), we adopted the revised version of the STrR clinical measure beginning with the PY 2021 ESRD QIP.

Commenters to the CY 2019 ESRD PPS proposed rule raised concerns about the validity of the modified STrR measure (NQF #2979) finalized for adoption beginning with PY 2021 (83 FR 56993 through 56994). Commenters specifically stated that due to the new level of coding specificity required under the ICD–10–CM/PCS coding system, many hospitals were no longer accurately coding blood transfusions. The commenters further stated that because the STrR clinical measure was calculated using hospital data, the rise of inaccurate blood transfusion coding by hospitals had negatively affected the validity of the STrR measure (83 FR 56993 through 56994).

In the CY 2020 ESRD PPS final rule (84 FR 60720 through 60723), we finalized our proposal to convert the STrR clinical measure to a reporting measure while we examined these validity concerns. Accordingly, we finalized that, beginning with PY 2022, we would score the STrR measure so that facilities that meet previously finalized minimum data and eligibility requirements would receive a score on the STrR reporting measure based on the successful reporting of data, not on the values actually reported. We stated our desire to ensure that the Program's scoring methodology results in fair and reliable STrR measure scores because those scores are linked to facilities' TPS and possible payment reductions. We also stated our belief that the most appropriate way to continue fulfilling the statutory requirement to include a measure of anemia management in the Program while ensuring that facilities are not adversely affected during our

[258] Ibid.

[259] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html* on January 7, 2022.

continued examination of the measure was to convert the STrR clinical measure to a reporting measure.

In November 2020, the NQF renewed its endorsement of the STrR clinical measure after performing an ad hoc review based on updates we made to the measure's specifications to address coding and validity concerns. Under the revised STrR clinical measure, inpatient transfusion events are identified using a broader definition that includes revenue center codes only, ICD procedure codes (alone or with revenue codes), or value codes alone or in combination. We believe that these updates would result in identification of a greater number of inpatient transfusion events compared to the previously implemented STrR clinical measure. In addition, the revised STrR clinical measure would effectively mitigate a provider coding bias that was exacerbated by the conversion from ICD–9 to ICD–10 code sets in late CY 2015.

In light of the NQF's endorsement and adoption of the updated STrR clinical measure specifications, we are proposing to convert the STrR reporting measure to the revised STrR clinical measure using the revised specifications that were endorsed by the NQF. We believe that previous validity concerns have been adequately examined and addressed, that facilities have had sufficient time to gain experience with the updated measure specifications through reporting the updated measure for Dialysis Facility Compare, and converting back to the STrR clinical measure would be consistent with our intent to more closely align with NQF measure specifications where feasible (84 FR 60724).

In addition to our proposal to convert the STrR reporting measure to a clinical measure, we are also proposing to update the scoring methodology for the STrR clinical measure so that facilities that meet previously finalized minimum data and eligibility requirements would receive a score on the STrR clinical measure based on the actual clinical values reported by the facility, rather than the successful reporting of the data. We are also proposing to express the proposed STrR clinical measure as a rate, rather than as a ratio. We believe that converting the STrR clinical measure to be expressed as a rate would help providers and patients better understand a facility's performance on the measures, and would be more intuitive for a facility to track its performance from year to year. To assess the impact of expressing STrR measure results as rates, we multiplied the facility level STrR by the national average transfusion rate. Our analysis found that the difference between the distribution of STrR measure scores expressed as a ratio and expressed as a rate was generally less than 1 percent. Therefore, we believe that expressing STrR measure results as a rate would not result in different ESRD QIP scores. This approach would also align with our technical updates to the SHR clinical measure and the SRR clinical measure, as discussed in section IV.D of this proposed rule.

We welcome public comment on our proposals.

c. Proposal To Convert the Hypercalcemia Clinical Measure to a Reporting Measure Beginning With PY 2025

Section 1881(h)(2)(A)(iv)(II) of the Act states that the measures specified for the ESRD QIP must include, to the extent feasible, measures of bone mineral metabolism. Abnormalities of bone mineral metabolism are exceedingly common and contribute significantly to morbidity and mortality in patients with advanced Chronic Kidney Disease (CKD). Many studies have associated disorders of mineral metabolism with mortality, fractures, cardiovascular disease, and other morbidities. Therefore, in the CY 2014 ESRD PPS final rule (78 FR 72200 through 72203), we adopted the Hypercalcemia clinical measure as part of the ESRD QIP measure set, which we believed would encourage adequate management of bone mineral metabolism and disease in patients with ESRD.

In recent years, we have received numerous public comments expressing concern about the role and weight of the Hypercalcemia clinical measure in the ESRD QIP. Many stakeholders have indicated that they believe the measure is topped out, pointing out that the NQF has placed the measure in Reserve Status because of high facility performance and minimal room for improvement. As a result, the ability to distinguish meaningful differences in performance between facilities is substantially reduced because small random variations in measure rates can result in different scores. Others have expressed concern about whether the Hypercalcemia clinical measure is the best measure in the bone mineral metabolism domain to impact patient outcomes.

Taking into account these persistent concerns expressed by stakeholders, we are currently examining the continued viability of the Hypercalcemia clinical measure as part of the ESRD QIP measure set. We also acknowledge that there may be other measures of bone mineral metabolism that are more informative or effective than the Hypercalcemia clinical measure, such as the serum phosphorus measure.[260]

Although recent annual measure analyses have indicated that the Hypercalcemia clinical measure may not be fully topped out based on the statistical criteria that we adopted in the CY 2015 ESRD PPS final rule (79 FR 66174), they also indicate that the measure is very close to being topped out. Under our previously adopted methodology, a clinical measure is considered to be topped out if national measure data show (1) statistically indistinguishable performance levels at the 75th and 90th percentiles; and (2) a truncated coefficient of variation (TCV) of less than or equal to 0.1. To determine whether a clinical measure is topped out, we initially focus on the top distribution of facility performance on each measure and note if their 75th and 90th percentiles are statistically indistinguishable. Then, to ensure that we properly account for the entire distribution of scores, we analyze the truncated coefficient of variation (TCV) for the measure. Based on a 2017 analysis using CY 2015 CROWNWeb measure data, the Hypercalcemia clinical measure did not meet both conditions. Although the TCV was less than 1 percent, the difference between the 75th percentile (0.91) was statistically distinguishable from the 90th percentile (0.32). However, given that the TCV was so low and was calculated by removing the lower and upper 5th percentiles, we believe it is possible that certain outliers in the 90th percentile could have skewed the statistically distinguishable part of the topped out analysis. In other words, although the Hypercalcemia clinical measure is not considered topped out based on our previously adopted methodology, we believe that it is very close to being topped out based on the available data and are concerned that small differences in measure performance may disproportionately impact a facility's score on the measure.

Therefore, we are proposing to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025 while we explore possible replacement measures that would be more clinically meaningful for purposes of quality improvement. We are also proposing to update the scoring methodology so that facilities that meet previously finalized minimum data and eligibility requirements would receive a

[260] CMS ESRD QIP PY 2020 Final Measure Technical Specifications. Accessed May 18, 2022 at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/PY-2020-Technical-Specification.pdf.*

score on the Hypercalcemia reporting measure based on the successful reporting of the data, rather than the actual clinical values reported by the facility. Facilities would be scored using the following equation, beginning in PY 2025:

$$\left(\frac{\text{number of patient-months successfully reporting data}}{\text{number of eligible patient-months}} \times 12\right) - 2$$

If finalized, the Hypercalcemia reporting measure would be in our proposed Reporting Measure Domain, which we discuss in section IV.E.2.

We welcome public comments on our proposal to convert the Hypercalcemia clinical measure to a reporting measure, beginning in PY 2025.

2. Proposed Revisions To Measure Domains and to the Domain and Measure Weights Used To Calculate the Total Performance Score (TPS) Beginning With the PY 2025 ESRD QIP

In the CY 2019 ESRD PPS final rule (83 FR 56991 through 56992), we finalized revisions to the ESRD QIP measure domains. Specifically, we eliminated the Reporting Domain and reorganized the Clinical Domain into three distinct domains: Patient & Family Engagement Domain, Care Coordination Domain, and Clinical Care Domain. We stated that adopting these topics as separate domains would result in a measure set that is more closely aligned with the priority areas in the Meaningful Measures Framework.[261] We also continued use of the Patient Safety Domain, which aligns with the Meaningful Measures Framework priority to make care safer by reducing harm caused in the delivery of care. In that rule, we finalized our proposal to eliminate the Reporting Measure Domain from the ESRD QIP scoring methodology, beginning in PY 2021, because there would no longer be any measures in that domain as a result of our finalized proposals to reassign the Ultrafiltration Rate and Clinical Depression Screening and Follow-Up Reporting measures to the Clinical Care Measure Domain and the Care Coordination Measure Domain, respectively (83 FR 56991 through 56997).

In the CY 2019 ESRD PPS final rule, we also stated our intent to reassess how the finalized ESRD QIP measure domains and domain weights affect TPSs awarded under the Program in the future (83 FR 56995). We take numerous factors into account when determining appropriate domain and measure weights, including clinical evidence, opportunity for improvement, clinical significance, and patient and provider burden. We also consider criteria previously used to determine appropriate domain and measures weights, including: (1) The number of measures and measure topics in a proposed domain; (2) how much experience facilities have had with the measures and measure topics in a proposed domain; and (3) how well the measures align with CMS's highest priorities for quality improvement for patients with ESRD (79 FR 66214) (that is, the Meaningful Measures Framework priorities, which includes our preferred emphasis on patient outcomes).

Currently, ESRD QIP measures are weighted and distributed across four measure domains: Patient & Family Engagement, Care Coordination, Clinical Care, and Safety. Based on changes to the measure set since PY 2021, including adoption of the Medication Reconciliation (MedRec) reporting measure, the PPPW clinical measure, and the measure-related proposals in this proposed rule, we have reassessed the impact of the ESRD QIP measure domains and domain weights on TPSs, and we believe it is necessary to increase incentives for improving performance by increasing the weights on measures where there is the most room for improvement, especially on patient clinical outcomes. Therefore, we are proposing to create a new Reporting Measure Domain which would include the four current reporting measures in the ESRD QIP measure set, as well as the proposed COVID–19 HCP Vaccination reporting measure and the proposed Hypercalcemia reporting measure. We note that we are proposing to convert the STrR reporting measure to a clinical measure, as discussed in section IV.E.1.b of this proposed rule, and as a result, we are proposing that the proposed STrR clinical measure would be placed in the Clinical Care Measure Domain.

We are also proposing to update the domain weights and individual measure weights in the Care Coordination Domain, Clinical Care Domain, and Safety Domain accordingly to accommodate the new Reporting Measure Domain and individual reporting measures therein. As the ESRD QIP measure set has evolved over the years, we believe this would help to address concerns regarding the impact of individual measure performance on a facility's TPS, while also further incentivizing improvement on clinical measures. For a comparison of current and proposed measure domains and weighting, please see Table 19 and Table 20.

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[261] CMS website, Meaningful Measures Framework. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy*.

TABLE 19: Current ESRD QIP Measure Domains and Weights

Measure/Measure Topics By Subdomain	Measure Weight as Percent of TPS
Patient and Family Engagement Measure Domain	**15.00**
ICH CAHPS measure	15.00
Care Coordination Measure Domain	**30.00**
SHR clinical measure	12.00
SRR clinical measure	12.00
PPPW measure	4.00
Clinical Depression and Follow-Up reporting measure	2.00
Clinical Care Measure Domain	**40.00**
Kt/V Dialysis Adequacy Comprehensive Measure	9.00
Vascular Access Type Measure Topic	12.00
STrR measure	10.00
Hypercalcemia measure	3.00
Ultrafiltration Rate measure	6.00
Safety Measure Domain	**15.00**
NHSN BSI clinical measure	8.00
MedRec measure	4.00
NHSN Dialysis Event reporting measure	3.00

TABLE 20: Proposed ESRD QIP Measure Domains and Weights

Measure/Measure Topics By Subdomain	Measure Weight as Percent of TPS
Patient and Family Engagement Measure Domain	**15.00**
ICH CAHPS measure	15.00
Care Coordination Measure Domain	**30.00**
SHR clinical measure	12.00
SRR clinical measure	12.00
PPPW measure	6.00
Clinical Care Measure Domain	**35.00**
Kt/V Dialysis Adequacy Comprehensive Measure	11.00
Vascular Access Type Measure Topic	12.00
STrR clinical measure*	12.00
Safety Measure Domain	**10.00**
NHSN BSI clinical measure	10.00
Reporting Measure Domain	**10.00**
Clinical Depression and Follow-Up reporting measure	1.67
Hypercalcemia reporting measure**	1.67
Ultrafiltration Rate reporting measure	1.67
MedRec reporting measure	1.67
NHSN Dialysis Event reporting measure	1.67
COVID-19 HCP Vaccination reporting measure***	1.67

* We are proposing to convert the STrR reporting measure to a clinical measure beginning in PY 2025, as discussed in section IV.E.1.b of this proposed rule.
**We are proposing to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025, as discussed in section IV.E.1.c of this proposed rule.
***We are proposing to adopt the COVID-19 HCP Vaccination measure beginning in PY 2025, as discussed in section IV.E.1.a of this proposed rule.

We welcome public comment on our proposal to create a new Reporting Domain and to update the existing domains and measure weights used to calculate the TPS, beginning with PY 2025.

3. Estimated Performance Standards for the PY 2025 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as required by section 1881(h)(4)(B) of the Act, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. We refer

readers to the CY 2013 ESRD PPS final rule (76 FR 70277) for a discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We define the terms ''achievement threshold,'' ''benchmark,'' ''improvement threshold,'' and ''performance standard'' in our regulations at 42 CFR 413.178(a)(1), (3), (7), and (12), respectively.

In the CY 2022 ESRD PPS final rule (86 FR 61927), we set the performance period for the PY 2025 ESRD QIP as CY 2023 and the baseline period as CY 2021. We note that, for the six measures we are proposing to suppress in section IV.B.2 of this proposed rule, we would continue to use CY 2019 data as the baseline period for those measures. We believe that this is consistent with our established policy to use the prior year's numerical values for the performance standards if the most recent full CY's final numerical values are worse. For the measures that we are proposing to suppress for PY 2023, this would result in no measure data that could be used for CY 2021 baseline period. Therefore, this would result in worse performance standards for those suppressed measures in PY 2025. In this proposed rule, we are estimating the performance standards for the PY 2025 clinical measures in Table 21 using data from CY 2019, which is the most recent data available. We intend to update these standards for the non-suppressed measures, using CY 2021 data, in the CY 2023 ESRD PPS final rule.

TABLE 21: Estimated Performance Standards for the PY 2025 ESRD QIP Clinical Measures Using the Most Recently Available Data

Measure	Achievement Threshold (15th Percentile of National Performance)	Median (50th Percentile of National Performance)	Benchmark (90th Percentile of National Performance)
Vascular Access Type (VAT)			
Standardized Fistula Rate	53.29%	64.36%	76.77%
Catheter Rate	18.35%	11.04%	4.69%
Kt/V Comprehensive	94.33%	97.61%	99.42%
Hypercalcemia**	1.54%	0.49%	0.00%
Risk-Standardized Readmission Rate[a]	34.27	26.97	17.02
NHSN BSI	1.193	0.516	0
Risk-Standardized Hospitalization Rate[b]	187.80	148.33	105.54
Risk-Standardized Transfusion Rate[b]	47.45	27.01	10.56
PPPW	8.12%*	16.73%*	33.90%*
ICH CAHPS: Nephrologists' Communication and Caring	58.20%	67.90%	79.15%
ICH CAHPS: Quality of Dialysis Center Care and Operations	54.64%	63.08%	72.66%
ICH CAHPS: Providing Information to Patients	74.49%	81.09%	87.80%
ICH CAHPS: Overall Rating of Nephrologists	49.33%	62.22%	76.57%
ICH CAHPS: Overall Rating of Dialysis Center Staff	50.02%	63.37%	78.30%
ICH CAHPS: Overall Rating of the Dialysis Facility	54.51%	69.04%	83.72%

*Values are the same final performance standards for those measures for PY 2024. In accordance with our longstanding policy, we are using those numerical values for those measures for PY 2025 because they are higher standards than the PY 2025 numerical values for those measures.

**We are proposing to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025, as discussed in section IV.E.1.c of this proposed rule. If this proposal is finalized, we would update the table accordingly in the final rule.

[a]Rate calculated as a percentage of hospital discharges

[b]Rate per 100 patient-years

Data sources: VAT measures: 2019 CROWNWeb; SRR, SHR: 2019 Medicare claims; Kt/V: 2019 CROWNWeb; Hypercalcemia: 2019 CROWNWeb; NHSN: 2019 CDC; ICH CAHPS: CMS 2019; PPPW: 2019 CROWNWeb and 2019 Organ Procurement and Transplantation Network (OPTN).

In addition, we summarize in Table 22 existing requirements for successful reporting on reporting measures in the PY 2025 ESRD QIP.

TABLE 22: Requirements for Successful Reporting on the PY 2025 ESRD QIP Reporting Measures

Measure	Reporting Frequency	Data Elements
Ultrafiltration	4 data elements are reported for every hemodialysis (HD) Kt/V session during the week of the monthly Kt/V draw, and the number of sessions of dialysis is reported monthly	• In-Center Hemodialysis (ICHD) Kt/V Date • Post-Dialysis Weight • Pre-Dialysis Weight • Delivered Minutes of blood urea nitrogen (BUN) Hemodialysis • Number of sessions of dialysis delivered by the dialysis unit to the patient in the reporting Month
MedRec	Monthly	• Date of the medication reconciliation. • Type of eligible professional who completed the medication reconciliation: o physician, o nurse, o advanced registered nurse practitioner (ARNP), o physician assistant (PA), o pharmacist, or o pharmacy technician personnel • Name of eligible professional
Clinical Depression Screening and Follow-Up	1 of 6 conditions reported annually	• Screening for clinical depression is documented as being positive and a follow-up plan is documented. • Screening for clinical depression documented as positive, a follow-up plan is not documented, and the facility possesses documentation that the patient is not eligible. • Screening for clinical depression documented as positive, the facility possesses no documentation of a follow-up plan, and no reason is given. • Screening for clinical depression documented as negative and no follow-up plan required. • Screening for clinical depression not documented, but the facility possesses documentation stating the patient is not eligible. • Clinical depression screening not documented, and no reason is given.
NHSN Dialysis Event	Monthly	Three types of dialysis events reported: • IV antimicrobial start; • positive blood culture; and • pus, redness, or increased swelling at the vascular access site.
STrR*		At least 10 patient-years at risk during the performance period.
Hypercalcemia**	Monthly	Total uncorrected serum or plasma calcium lab values
COVID-19 HCP Vaccination***	At least one week of data each month, submitted quarterly	Cumulative number of HCP eligible to work in the facility for at least one day during the reporting period and who received a complete vaccination course against SARS-CoV-2.

*We are proposing to convert the STrR reporting measure to a clinical measure beginning in PY 2025, as discussed in section IV.E.1.b of this proposed rule. If finalized, we would update this table in the final rule.
**We are proposing to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025, as discussed in section IV.E.1.c of this proposed rule.
***We are proposing to adopt the COVID-19 HCP Vaccination measure beginning in PY 2025, as discussed in section IV.E.1.a of this proposed rule.

4. Eligibility Requirements for the PY 2025 ESRD QIP

Our current minimum eligibility requirements for scoring the ESRD QIP measures are described in Table 23. We are not proposing any changes to these eligibility requirements for the PY 2025 ESRD QIP in this proposed rule.

TABLE 23: Eligibility Requirements for Scoring on ESRD QIP Measures

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Kt/V Comprehensive (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
VAT: Long-term Catheter Rate (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
VAT: Standardized Fistula Rate (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
Hypercalcemia (Clinical)*	11 qualifying patients	N/A	11-25 qualifying patients
NHSN BSI (Clinical)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	11-25 qualifying patients
NHSN Dialysis Event (Reporting)	11 qualifying patients	N/A	N/A
SRR (Clinical)	11 index discharges	N/A	11-41 index discharges
STrR (Reporting)**	10 patient-years at risk	N/A	N/A
SHR (Clinical)	5 patient-years at risk	N/A	5-14 patient-years at risk
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities would not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period	Before October 1 prior to the performance period that applies to the program year.	N/A
Depression Screening and Follow-Up (Reporting)	11 qualifying patients	Before April 1 of the performance period that applies to the program year.	N/A
Ultrafiltration (Reporting)	11 qualifying patients	Before April 1 of the performance period that applies to the program year.	N/A
MedRec (Reporting)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	N/A
PPPW (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
COVID-19 HCP Vaccination (Reporting)***	11 qualifying healthcare personnel	N/A	N/A

* We are proposing to convert the Hypercalcemia clinical measure to a reporting measure beginning in PY 2025, as discussed in section IV.E.1.c of this proposed rule.
**We are proposing to convert the STrR reporting measure to a clinical measure beginning in PY 2025, as discussed in section IV.E.1.b of this proposed rule. If finalized, we would update this table in the final rule.
***We are proposing to adopt the COVID-19 HCP Vaccination measure beginning in PY 2025, as discussed in section IV.E.1.a of this proposed rule.

5. Payment Reduction Scale for the PY 2025 ESRD QIP

Under our current policy, a facility does not receive a payment reduction for a payment year in connection with its performance under the ESRD QIP if it achieves a TPS that is at or above the minimum TPS (mTPS) that we establish for the payment year. We have defined the mTPS in our regulations at 42 CFR 413.178(a)(8) as, with respect to a payment year, the TPS that an ESRD

facility would receive if, during the baseline period it performed at the 50th percentile of national performance on all clinical measures and the median of national ESRD facility performance on all reporting measures.

Our current policy, which is codified at 42 CFR 413.177 of our regulations, also implements the payment reductions on a sliding scale using ranges that reflect payment reduction differentials of 0.5 percent for each 10 points that the facility's TPS falls below the mTPS (76 FR 634 through 635).

For PY 2025, based on available data, a facility must meet or exceed a mTPS of 55 in order to avoid a payment reduction. We note that the mTPS estimated in this proposed rule is based on data from CY 2019 instead of the PY 2025 baseline period (CY 2021) because CY 2021 data are not yet available.

We refer readers to Table 19 of this proposed rule for the estimated values of the 50th percentile of national performance for each clinical measure. Under our current policy, a facility that achieves a TPS below 55 would receive a payment reduction based on the TPS ranges indicated in Table 24.

TABLE 24: Estimated Payment Reduction Scale for PY 2025 Based on the Most Recently Available Data

Total performance score	Reduction (%)
100-55	0%
54-45	0.5%
44-35	1.0%
34-25	1.5%
24-0	2.0%

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We intend to update the mTPS for PY 2025, as well as the payment reduction ranges for that payment year, in the CY 2023 ESRD PPS final rule.

F. Updates for the PY 2026 ESRD QIP

1. Continuing Measures for the PY 2026 ESRD QIP

Under our previously adopted policy, the PY 2025 ESRD QIP measure set would also be used for PY 2026. We are not proposing to adopt any new measures beginning with the PY 2026 ESRD QIP.

2. Performance Period for the PY 2026 ESRD QIP

We continue to believe that 12-month performance and baseline periods provide us sufficiently reliable quality measure data for the ESRD QIP. Under this policy, we would adopt CY 2024 as the performance period and CY 2022 as the baseline period for the PY 2026 ESRD QIP.

We are not proposing any changes to this policy.

3. Performance Standards for the PY 2026 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as required by section 1881(h)(4)(B) of the Act, and must be established prior to the beginning of the performance period for the year involved, as required by section 1881(h)(4)(C) of the Act. We refer readers to the CY 2012 ESRD PPS final rule (76 FR 70277) for a discussion of the achievement and improvement standards that we have established for clinical measures used in the ESRD QIP. We define the terms ''achievement threshold,'' ''benchmark,'' ''improvement threshold,'' and ''performance standard'' in our regulations at 42 CFR 413.178(a)(1), (3), (7), and (12), respectively.

a. Performance Standards for Clinical Measures in the PY 2026 ESRD QIP

At this time, we do not have the necessary data to assign numerical values to the achievement thresholds, benchmarks, and 50th percentiles of national performance for the clinical measures because we do not have CY 2021 data. We intend to publish these numerical values, using CY 2021 data, in the CY 2023 ESRD PPS final rule.

b. Performance Standards for the Reporting Measures in the PY 2026 ESRD QIP

In the CY 2019 ESRD PPS final rule, we finalized the continued use of existing performance standards for the Screening for Clinical Depression and Follow-Up reporting measure, the Ultrafiltration Rate reporting measure, the NHSN Dialysis Event reporting measure, and the MedRec reporting measure (83 FR 57010 through 57011). We would continue use of these performance standards in PY 2026. In sections IV.E.1.c and IV.E.1.a of this proposed rule, we are proposing to convert the Hypercalcemia clinical measure to a reporting measure and to add the COVID–19 Vaccination Coverage among HCP reporting measure to the ESRD QIP measure set beginning with PY 2025, and would include these in the performance standards for reporting measures in the PY 2026 ESRD QIP if this proposal is finalized.

4. Scoring the PY 2026 ESRD QIP

a. Scoring Facility Performance on Clinical Measures

In the CY 2014 ESRD PPS final rule, we finalized policies for scoring performance on clinical measures based on achievement and improvement (78 FR 72215 through 72216). In the CY 2019 ESRD PPS final rule, we finalized a policy to continue use of this methodology for future payment years (83 FR 57011) and we codified these scoring policies at 42 CFR 413.178(e). In section IV.E.1.b of this proposed rule,

we are proposing to update our scoring methodology beginning with PY 2025.

b. Scoring Facility Performance on Reporting Measures

Our policy for scoring performance on reporting measures is codified at 42 CFR 413.178(e), and more information on our scoring policy for reporting measures can be found in the CY 2020 ESRD PPS final rule (84 FR 60728). We previously finalized policies for scoring performance on the NHSN Dialysis Event reporting measure in the CY 2018 ESRD PPS final rule (82 FR 50780 through 50781), as well as policies for scoring the MedRec reporting measure and Clinical Depression Screening and Follow-up reporting measure in the CY 2019 ESRD PPS final rule (83 FR 57011). We also previously finalized the scoring policy for the STrR reporting measure in the CY 2020 ESRD PPS final rule (84 FR 60721 through 60723). In the CY 2021 ESRD PPS final rule, we finalized our updated scoring methodology for the Ultrafiltration Rate reporting measure (85 FR 71468 through 71470). In section IV.E.1.c of this proposed rule, we are proposing to update our scoring methodology as part of our proposal to convert the Hypercalcemia clinical measure to a reporting measure beginning with PY 2025. We are also proposing to adopt a scoring methodology as part of our proposal to add the COVID–19 Vaccination Coverage among HCP reporting measure to the ESRD QIP measure set beginning with PY 2025, as discussed in section IV.E.1.a of this proposed rule.

5. Weighting the Measure Domains and the TPS for PY 2026

Under our current policy, we assign the Patient & Family Engagement Measure Domain a weight of 15 percent of the TPS, the Care Coordination Measure Domain a weight of 30 percent of the TPS, the Clinical Care Measure Domain a weight of 40 percent of the TPS, and the Safety Measure domain a weight of 15 percent of the TPS.

In the CY 2019 ESRD PPS final rule, we finalized a policy to assign weights to individual measures and a policy to redistribute the weight of unscored measures (83 FR 57011 through 57012). In the CY 2020 ESRD PPS final rule, we finalized a policy to use the measure weights we finalized for PY 2022 for the PY 2023 ESRD QIP and subsequent payment years, and also to use the PY 2022 measure weight redistribution policy for the PY 2023 ESRD QIP and subsequent payment years (84 FR 60728 through 60729).

In section IV.E.2 of this proposed rule, we are proposing the addition of a new Reporting Measure Domain, and we are proposing new weights for the four existing measure domains, beginning in PY 2025. If finalized, we would update the measure weights and domains and the TPS for PY 2026 accordingly in the final rule.

G. Requests for Information (RFI) on Topics Relevant to ESRD QIP

1. Request for Information on Quality Indicators for Home Dialysis Patients

In this proposed rule, we are seeking public comments on potential indicators of quality for patients who receive dialysis at home in order to support the use of home dialysis for ESRD patients where it is appropriate. While home-based dialysis may not meet the needs of every patient, home dialysis has clear benefits for those who are suitable candidates. Often, it may be more convenient for many ESRD patients, and survivability rates for home dialysis are comparable to those of transplant recipients and in-center hemodialysis.[262]

There are two general types of dialysis: hemodialysis (HD), in which an artificial filter outside of the body is used to clean the blood; and peritoneal dialysis (PD), in which the patient's peritoneum, covering the abdominal organs, is used as the dialysis membrane. HD is conducted at an ESRD facility, usually three times a week, or at a patient's home, often at a greater frequency. PD most commonly occurs at the patient's home. (Although PD can be furnished within an ESRD facility, it is very rare. For purposes of this RFI, we consider PD to be exclusively a home modality.) Assuming that either modality would be clinically appropriate, whether a patient selects HD or PD may depend on a number of factors, such as patient education before dialysis initiation, social and care partner support, socioeconomic factors, and patient perceptions and preference.[263] [264]

When Medicare began coverage for individuals with ESRD in 1973, more than 40 percent of dialysis patients in the U.S. were on home hemodialysis (HHD). More favorable reimbursement for outpatient dialysis and the introduction in the 1970s of continuous ambulatory peritoneal dialysis, which required less intensive training, contributed to a relative decline in HHD utilization.[265] Overall, the proportion of home dialysis patients in the U.S. declined from 1988 to 2012, with the number of home dialysis patients increasing at a slower rate relative to the total number of all dialysis patients. As cited in a U.S. Government Accountability Office (GAO) report, according to U.S. Renal Data System (USRDS) data, approximately 16 percent of the 104,000 dialysis patients in the U.S. received home dialysis in 1988; however, by 2012, the rates of HHD and PD utilization were 2 and 9 percent, respectively.[266]

Currently, the majority of ESRD patients receiving dialysis receive HD in an ESRD facility. At the end of 2016, 63.1 percent of all prevalent ESRD patients—meaning patients already diagnosed with ESRD—in the U.S. were receiving HD, 7.0 percent were being treated with PD, and 29.6 percent had a functioning kidney transplant.[267] Among HD cases, 98.0 percent used in-center HD, and 2.0 percent used HHD.[268] We note that once they are stable on a specific modality, patients are infrequently aware that they are able to change modalities. In 2018, 72 percent of Black ESRD patients received in-center hemodialysis versus only 57 percent of White patients. This data point may indicate that a greater number of white ESRD patients receive home dialysis than Black patients.[269]

Research suggests that dialyzing at home is associated with lower overall medical expenditures than dialyzing in-center. Key factors that may be related to lower expenditures include potentially lower rates of infection associated with dialysis treatment, fewer hospitalizations, cost differentials between PD and HD services and supplies, and lower operating costs for

[262] ASPE Report, Advancing American Kidney Health, p. 24. Available at *https://aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf.*

[263] Stack AG. Determinants of Modality Selection among Incident US Dialysis Patients: Results from a National Study. Journal of the American Society of Nephrology. 2002; 13: 1279–1287. Doi 1046–6673/1305–1279.

[264] Miskulin DC, et al. Comorbidity and Other Factors Associated With Modality Selection in Incident Dialysis Patients: The CHOICE Study. American Journal of Kidney Diseases. 2002; 39(2): 324–336. Doi 10.1053/ajkd.2002.30552.

[265] Blagg CR. A Brief History of Home Hemodialysis. Annals in Renal Replacement Therapy. 1996; 3: 99–105.

[266] United States Government Accountability Office. End Stage Renal Disease: Medicare Payment Refinements Could Promote Increased Use of Home Dialysis (GAO–16–125). October 2015.

[267] United States Renal Data System, Annual Data Report, 2018. Volume 2. Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. *https://www.usrds.org/2018/view/v2_01.aspx.*

[268] United States Renal Data System, Annual Data Report, 2018. Volume 2. Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. *https://www.usrds.org/2018/view/v2_01.aspx.*

[269] National Kidney Foundation. *https://www.kidney.org/news/newsroom/fsindex.* Accessed 11/15/2021.

dialysis providers for providing home dialysis.[270] [271] [272] [273] [274]

We believe that increasing rates of home dialysis has the potential to not only reduce Medicare expenditures, but also to preserve or enhance the quality of care for ESRD beneficiaries. In fact, recent studies show substantial support among nephrologists and patients for dialysis treatment at home.[275] [276] [277] [278] [279] Although some measures in the ESRD QIP apply to home dialysis facilities, certain measures do not apply to facilities that have high rates of home dialysis. For example, home dialysis facilities are generally not eligible for scoring on the ICH–CAHPS measure, the Long-Term Catheter Rate clinical measure, the Standardized Fistula Rate measure, and the NHSN BSI clinical measure. Therefore, many of these facilities are eligible for fewer measures than facilities that provide in-center hemodialysis only. As increasing numbers of ESRD patients use home dialysis therapies,[280] we are interested in learning more about potential indicators of quality of care for home dialysis patients that are not currently being captured by the ESRD QIP. Therefore, we are seeking comments on strategies to monitor and assess the quality of care delivered to patients who receive dialysis at home. We are also seeking comments on how to support more equitable access to home dialysis across different ESRD patient populations.

We welcome comments on these issues.

2. Request for Information on Potential Future Inclusion of Two Social Drivers of Health Measures

(1) Background

Our commitment to supporting facilities in building equity into their healthcare delivery practices centers on empowering their workforce to recognize and eliminate health disparities that disproportionately impact people with ESRD, such as, individuals who are members of racial and ethnic minority groups, have low incomes, and/or reside in rural areas. In the CY 2022 ESRD PPS final rule, we noted our intention to initiate additional request(s) for information (RFIs) on closing the health equity gap, including identification of the most relevant social risk factors for people with ESRD (86 FR 61930). Health-related social needs (HRSNs), defined as individual-level, adverse social conditions that negatively impact a person's health or healthcare, are significant risk factors associated with worse health outcomes as well as increased healthcare utilization.[281] We believe that consistently pursuing identification of HRSNs would have two significant benefits. First, because social risk factors disproportionately impact underserved communities, promoting screening for these factors could serve as evidence-based building blocks for supporting facilities and health systems in actualizing commitment to address disparities, improve health equity, and implement associated equity measures to track progress.[282] Second, these measures could support ongoing quality improvement initiatives by providing data with which dialysis providers would be able to stratify patient risk and organizational performance.

We are investigating potential integration of screening for health-related social needs into the ESRD QIP measure set. This type of screening was the subject of the recently ended Accountable Health Communities (AHC) Model, which was implemented by the CMS Innovation Center.[283] The Innovation Center developed the AHC Model based on evidence that addressing health-related social needs (HRSNs) through enhanced linkages between health systems and community-based organizations can improve health outcomes and reduce costs.[284] HRSNs, defined as individual-level social conditions that negatively impact a person's health, are significant risk factors associated with adverse health outcomes and increased healthcare utilization, including excessive emergency department (ED) visits and avoidable hospitalizations.[285] [286] Unmet HRSNs, such as food insecurity, inadequate or unstable housing, and inadequate transportation may increase risk for onset of chronic conditions, such as ESRD, and accelerate exacerbation of related adverse health outcomes.[287] [288] [289]

[270] Walker R, Marshall MR, Morton RL, McFarlane P, Howard K. The cost-effectiveness of contemporary home hemodialysis modalities compared with facility hemodialysis: A systematic review of full economic evaluations. Nephrology. 2014; 19: 459–470 doi: 10.1111/nep.12269.

[271] Walker R, Howard K, Morton R. Home hemodialysis: A comprehensive review of patient-centered and economic considerations. ClinicoEconomics and Outcomes Research. 2017; 9: 149–161.

[272] Howard K, Salkeld G, White S, McDonald S, Chadban S, Craig J, Cass A. The cost effectiveness of increasing kidney transplantation and home-based dialysis. Nephrology. 2009; 14: 123–132 doi: 10.1111/j.1440–1797.2008.01073.x.

[273] Quinn R, Ravani P, Zhang X, Garg A, Blake P, Austin P, Zacharias JM, Johnson JF, Padeya S, Verreli M, Oliver M. Impact of Modality Choice on Rates of Hospitalization in Patients Eligible for Both Peritoneal Dialysis and Hemodialysis. Peritoneal Dialysis International. 2014; 34(1): 41–48 doi: 10.3447/pdi.2012.00257.

[274] Sinnakirouchenan R, Holley, J. Peritoneal Dialysis Versus Hemodialysis: Risks, Benefits, and Access Issues. Advances in Chronic Kidney Disease. 2011; 18(6): 428–432. doi: 10.1053/j.ackd.2011.09.001.

[275] Rivara MB, Mehrotra R. The Changing Landscape of Home Dialysis in the United States. Current Opinion in Nephrology and Hypertension.2014; 23(6):586–591.doi:10.1097/MNH0000000000000066.

[276] Mehrotra R, Chiu YW, Kalantar-Zadeh K, Bargman J, Vonesh E. Similar Outcomes With Hemodialysis and Peritoneal Dialysis in Patients With End-Stage Renal Disease. Archives of Internal Medicine. 2011; 171(2): 110–118. Doi:10.1001/archinternmed.2010.352.

[277] Ghaffarri A, Kalantar-Zadeh K, Lee J, Maddux F, Moran J, Nissenson A. PD First: Peritoneal Dialysis as the Default Transition to Dialysis Therapy. Seminars in Dialysis. 2013; 26(6): 706–713. doi: 10.1111/sdi.12125.

[278] Ledebo I, Ronco C. The best dialysis therapy? Results from an international survey among nephrology professionals. Nephrology Dialysis Transplantation.2008;6:403–408.doi:10.1093/ndtplus/sfn148.

[279] Schiller B, Neitzer A, Doss S. Perceptions about renal replacement therapy among nephrology professionals. Nephrology News & Issues. September 2010; 36–44.

[280] United States Renal Data System, 2018 Annual Data Report. Available at *https://www.usrds.org/2018/view/v2_01.aspx.*

[281] Centers for Medicare & Medicaid Services. (2021). A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. June 2021. Available at: *https://innovation.cms.gov/media/document/ahcm-screeningtool-companion.* Accessed: November 23, 2021.

[282] American Hospital Association. (2020). Health Equity, Diversity & Inclusion Measures for Hospitals and Health System Dashboards. December 2020. Accessed: January 18, 2022. Available at: *https://ifdhe.aha.org/system/files/media/file/2020/12/ifdhe_inclusion_dashboard.pdf.*

[283] Additional information about the Accountable Health Communities Model is available at: *https://innovation.cms.gov/innovation-models/ahcm.*

[284] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt.*

[285] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b.*

[286] Alley, D. E., C. N. Asomugha, P. H. Conway, and D. M. Sanghavi. 2016. Accountable Health Communities—Addressing Social Needs through Medicare and Medicaid. The New England Journal of Medicine 374(1):8–11. Available at: *https://doi.org/10.1056/NEJMp1512532.*

[287] Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

[288] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://care.diabetesjournals.org/lookup/doi/10.2337/dci20-0053.*

[289] Laraia, B.A. (2013). Food Insecurity and Chronic Disease. Advances in Nutrition, 4: 203–212, doi: 10.3945/an.112.003277.

We believe consistent identification of HRSNs among people with ESRD would have two significant benefits that would contribute to reduction in health disparities and improvements in quality and efficiency of dialysis care delivery. First, due to the association between chronic condition risk and HRSNs, screening for these needs could serve as evidence-based building blocks for supporting ESRD facilities and health systems in addressing persistent disparities and tracking progress towards closing the health equity gap in the ESRD population. Second, these measures would support ongoing quality improvement initiatives, specifically, care coordination for ESRD patients, by providing data with which to potentially stratify quality performance in dialysis providers. This is especially relevant in settings where a disproportionate number of patients have HRSNs and adverse healthcare outcomes, including hospital readmissions, that result in higher penalties related to diminished quality performance.[290] [291] We believe these measures align with *The CMS Quality Strategy Goals* around effective care coordination and prevention and treatment of chronic conditions.[292] We note that advancing health equity by addressing the health disparities that underlie the country's health system is one of our strategic pillars and a Biden-Harris Administration priority.[293] In this proposed rule, we seek public comment on the potential future inclusion of two related measures discussed later in this section.

(2) Screening for Social Drivers of Health Measure

Significant and persistent health disparities in the United States result in adverse health outcomes for people with ESRD.[294] [295] The COVID–19 pandemic has illuminated the detrimental interaction between HRSNs, adverse health outcomes, and healthcare utilization in the United States.[296] [297] Individuals from racial and ethnic minority groups and with lower incomes are less likely to receive recommended care for CKD risk factors and are also less likely to reduce CKD risk through recommended treatment goals.[298] [299] [300] [301] Consequently, some groups are more likely to progress from CKD to ESRD and less likely to be under the care of a nephrologist before starting dialysis.[302] Individuals from racial and ethnic minority groups with ESRD are more likely to have 30-day hospital readmissions when compared to non-Hispanic White patients.[303] Emerging evidence has shown that specific social risk factors are directly associated with health outcomes and healthcare utilization and costs.[304] [305] [306] [307] Of particular concern among people with ESRD are barriers to treatment prior to and after diagnosis, including inadequate access to healthy foods, unstable housing, limited transportation, and community safety concerns.[308] [309]

We believe improvement in care coordination between ESRD facilities, hospitals, and community-based organizations would yield better health outcomes for people with ESRD and quality performance for dialysis and other healthcare providers. Recognizing the importance of social drivers of health, this year we have proposed to include social drivers of health screening measures in the Hospital Inpatient Quality Reporting Program (87 FR 28497 through 28506). We believe that screening for social drivers of health would similarly help inform facilities and other healthcare providers of the impact of HRSNs in people with ESRD, including their health outcomes and healthcare utilization. The measure would assess the proportion of adult patients who are screened for social drivers of health in five core domains, including food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

The goal is to lay the groundwork for potential future measures that focus on the development of an action plan to address these HRSNs, including efficiently navigating patients to available resources and strengthening the system of community-based supports where resources are lacking. Collecting baseline data via this measure would be crucial in informing design of future measures that could enable us to set appropriate performance targets. While widespread interest in addressing HRSNs exists, action is inconsistent, specifically in ESRD facilities. We are exploring potential future inclusion of social

[290] National Academies of Sciences, Engineering, and Medicine.2017. *Accounting for social risk factors in Medicare payment.* Washington, DC: The National Academies Press. doi: 10.17226/23635.

[291] Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

[292] Centers for Medicare & Medicaid Services. (2021) CMS' Quality Strategy. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy.*

[293] Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Centers for Medicare & Medicaid. Available at: *https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms.*

[294] United States Renal Data System. 2021 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States.* National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2021.

[295] Weinhandl, E.D., Wetmore, J.B., Peng, Y., Liu, J., Gilbertson, D.T., et al., (2021). Initial Effects of COVID–19 on Patient with ESKD. Journal of the American Society of Nephrology 32: 1444–1453. doi: *https://doi.org/10.1681/ASN.2021010009.*

[296] Centers for Disease Control. CDC COVID–19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID–19 Disparities and Achieving Health Equity. July 2020. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html.* Accessed November 17, 2021.

[297] Weinhandl, E.D., Wetmore, J.B., Peng, Y., Liu, J., Gilbertson, D.T., et al., (2021). Initial Effects of COVID–19 on Patient with ESKD. Journal of the American Society of Nephrology 32: 1444–1453. doi: *https://doi.org/10.1681/ASN.2021010009.*

[298] United States Renal Data System. 2021 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States.* National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2021.

[299] Benjamin O, Lappin SL. End-Stage Renal Disease. [Updated 2021 Sep 16]. In: Stat Pearls [internet]. Treasure Island (FL): StatPearls Publishing; 2022. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK499861/.*

[300] Norris, K.C., Williams, S.F., Rhee, C.M., Nicholas, S.B., Kovesdy, C.P., et al. (2017). Hemodialysis Disparities in African Americans: The Deeply Integrated Concept of Race in the Social Fabric of Our Society. Seminars in Dialysis 30(3):213–223. doi:10.1111/sdi.12589.

[301] CMS (2021). Chronic Kidney Disease Disparities: Educational Guide for Primary Care. Available at: *https://www.cms.gov/files/document/chronic-kidney-disease-disparities-educational-guide-primary-care.pdf.*

[302] Norton, J.M., Moxey-Mims, M.M., Eggers, P.W., Narva, A.S., Star, R.A., Kimmel, P.L., & Rodgers, G.P. (2016). Social Determinants of Racial Disparities in CKD. Journal of the American Society of Nephrology: JASN, 27(9), 2576–2595. *https://doi.org/10.1681/ASN.2016010027.*

[303] CMS (2014). Health Disparities Among Aged ESRD Beneficiaries, 2014. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/ESRD-Infographic.pdf.*

[304] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://care.diabetesjournals.org/lookup/doi/10.2337/dci20-0053.*

[305] Dean, E.B., French, M.T., Mortensen, K. (2020). Health Services Research 55 (Supplement 2): 883–893. doi: 10.1111/1475–6773.13283.

[306] Berkowitz, S.A., Kalkhoran, S., Edwards, S.T., Essien, U.R., Baggett, T.P. (2018). Unstable Housing and Diabetes-Related Emergency Department Visits and Hospitalization: A Nationally Representative Study of Safety-Net Clinic Patients. Diabetes Care 41: 933–939. *https://doi.org/10.2337/dc17-1812.*

[307] National Academies of Sciences, Engineering, and Medicine 2019. *Dialysis Transportation: The Intersection of Transportation and Healthcare.* Washington, DC: The National Academies Press. *https://doi.org/10.17226/25385.*

[308] *Ibid.*

[309] CMS (2021). Chronic Kidney Disease Disparities: Educational Guide for Primary Care. Available at: *https://www.cms.gov/files/document/chronic-kidney-disease-disparities-educational-guide-primary-care.pdf.*

drivers of health screening measures to the ESRD QIP. Therefore, we are seeking public comment on adding a new measure, Screening for Social Drivers of Health, to the ESRD QIP measure set in the next rulemaking cycle. The measure would assess the proportion of a facility's patients that are screened for one or more social drivers of health in the five core domains.

We believe facilities should screen for HRSNs among their patients to assess and increase the effectiveness of care coordination. Referral to community-based organizations can potentially reduce avoidable hospitalizations and disruptions to dialysis care. Data demonstrate that an overwhelming majority of people with ESRD travel outside their homes for dialysis three times per week, round trip, and that transportation challenges contribute to shortened treatment episodes and adverse health outcomes.[310] [311] We believe screening for HRSNs like transportation in people with ESRD and targeted care coordination that links them to community-based services could improve health outcomes in this population. We also believe that publishing social drivers of health screening rates would be helpful to many patients who need additional care coordination but may experience reluctance in seeking assistance due to concerns for personal stigmatization. Under our Meaningful Measures Framework, the Screening for Social Drivers of Health measure would address the quality priority ''Promoting Effective Prevention and Treatment of Chronic Disease'' through the Meaningful Measures Area ''Management of Chronic Conditions.''

(3) Screen Positive Rate for Social Drivers of Health Measure

We believe it is important to screen patients with ESRD for HRSNs that can negatively impact health outcomes and contribute to avoidable hospitalizations. Unmet HRSNs can interrupt dialysis treatment and other routine care, including preventive health screenings, that is essential for ESRD-related conditions. Many patients treated in ESRD facilities have other chronic conditions that require consistent, multidisciplinary care to maintain their health.[312] [313] Household food insecurity has been associated with reliance on energy-dense foods which increase risks for onset of diabetes and hypertension, the leading causes of ESRD.[314] Housing instability and transportation difficulties both contribute to interruptions in dialysis care which leads to avoidable hospitalizations.[315] [316] Additionally, the COVID–19 pandemic has highlighted associations between disproportionate health risk, hospitalization, and adverse health outcomes.[317] [318] Capturing HRSN data may facilitate strengthening of linkages between facilities, medical providers (inpatient and outpatient), and community-based organizations which potentially could enhance care coordination for this group. Therefore, we are seeking public comment on the possible addition of a new measure, Screen Positive Rate for Social Drivers of Health, to the ESRD QIP measure set in future rulemaking. The measure would assess the proportion of patients who screen positive for HRSNs in five core domains, including food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. We also believe that publishing screen positive rates for social drivers of health would be helpful to many patients who need additional care coordination but may experience reluctance in seeking assistance due to concerns for personal stigmatization. Under our Meaningful Measures Framework, the Screening for Social Drivers of Health measure would address the quality priority ''Promoting Effective Prevention and Treatment of Chronic Disease'' through the Meaningful Measures Area ''Management of Chronic Conditions.''

We welcome public comment on potentially adding these two related Social Drivers of Health measures to the ESRD QIP measure set. We also welcome public comment on data collection, submission, and reporting for these two measures.

3. Request for Information on Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs

a. Background

Significant and persistent inequities in healthcare outcomes exist in the United States. Belonging to a racial or ethnic minority group; being a member of a religious minority; living with a disability; being a member of the LGBTQ+ community; living in a rural area; or being near or below the poverty level, are often associated with worse health outcomes.[319] [320] [321] [322] [323] [324] [325] [326] [327] We are committed to achieving equity in healthcare outcomes for our

[310] *Ibid.*

[311] United States Renal Data System. 2021 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States.* National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2021.

[312] Benjamin O, Lappin SL. End-Stage Renal Disease. [Updated 2021 Sep 16]. In: Stat Pearls [internet]. Treasure Island (FL): StatPearls Publishing; 2022. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK499861/.*

[313] Norris, K.C., Williams, S.F., Rhee, C.M., Nicholas, S.B., Kovesdy, C.P., et al. (2017). Hemodialysis Disparities in African Americans: The Deeply Integrated Concept of Race in the Social Fabric of Our Society. Seminars in Dialysis 30(3):213–223. doi:10.1111/sdi.12589.

[314] Laraia, B.A. (2013). Food Insecurity and Chronic Disease. Advances in Nutrition, 4: 203–212, doi: 10.3945/an.112.003277.

[315] United States Renal Data System. 2021 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States.* National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2021.

[316] National Academies of Sciences, Engineering, and Medicine 2019. *Dialysis Transportation: The Intersection of Transportation and Healthcare.* Washington, DC: The National Academies Press. *https://doi.org/10.17226/25385.*

[317] Centers for Disease Control. CDC COVID–19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID–19 Disparities and Achieving Health Equity. July 2020. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html.* Accessed November 17, 2021.

[318] Weinhandl, E.D., Wetmore, J.B., Peng, Y., Liu, J., Gilbertson, D.T., et al., (2021). Initial Effects of COVID–19 on Patient with ESKD. Journal of the American Society of Nephrology 32: 1444–1453. doi: *https://doi.org/10.1681/ASN.2021010009.*

[319] Joynt KE, Orav E, Jha AK. (2011). Thirty-day readmission rates for Medicare beneficiaries by race and site of care. JAMA, 305(7):675–681.

[320] Milkie Vu et al. Predictors of Delayed Healthcare Seeking Among American Muslim Women, Journal of Women's Health 26(6) (2016) at 58; S.B. Nadimpalli, et al., The Association between Discrimination and the Health of Sikh Asian Indians.

[321] Lindenauer PK, Lagu T, Rothberg MB, et al. (2013). Income inequality and thirty-day outcomes after acute myocardial infarction, heart failure, and pneumonia: Retrospective cohort study. British Medical Journal, 346.

[322] Trivedi AN, Nsa W, Hausmann LRM, et al. (2014). Quality and equity of care in U.S. hospitals. New England Journal of Medicine, 371(24):2298–2308.

[323] Polyakova, M., et al. (2021). Racial disparities in excess all-cause mortality during the early COVID–19 pandemic varied substantially across states. Health Affairs, 40(2): 307–316.

[324] Rural Health Research Gateway. (2018). Rural communities: age, income, and health status. Rural Health Research Recap. Available at: *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-incomehealth-status-recap.pdf.*

[325] HHS Office of Minority Health. (2020). Progress Report to Congress: 2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities. Available at: *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[326] Heslin, KC, Hall, JE. (2021). Sexual Orientation Disparities in Risk Factors for Adverse COVID–19-Related Outcomes, by Race/Ethnicity—Behavioral Risk Factor Surveillance System, United States, 2017–2019. MMWR Morb Mortal Wkly Rep 2021;70:149–154. Available at: *https://www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.*

[327] Poteat TC, Reisner SL, Miller M, Wirtz AL. (2020). COVID–19 vulnerability of transgender women with and without HIV infection in the Eastern and Southern U.S. preprint. medRxiv. 2020;2020.07.21. 20159327. doi:10.1101/2020.07.21.20159327.

beneficiaries by supporting healthcare providers' quality improvement activities to reduce health disparities, enabling beneficiaries to make more informed decisions, and promoting healthcare provider accountability for healthcare disparities.[328]

Health equity is an important component of an equitable society. Equity, as defined in Executive Order 13985, is ''the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.'' [329]

We define health equity as the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, religion, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes. We are working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our beneficiaries need to thrive.[330]

Such disparities in health outcomes and healthcare access are the result of multiple factors including differences in access to routine dialysis and primary care which contribute to health disparities among patients with ESRD. We discussed the impact of these disparities on patients with ESRD in our request for information on closing the health equity gap in the CY 2022 ESRD PPS proposed rule (86 FR 36362). Because we are working toward the goal of all ESRD patients receiving high quality dialysis treatment and other healthcare, irrespective of individual characteristics, we are committed to supporting dialysis providers and health systems in building a culture of equity that focuses on educating and empowering the healthcare workforce to recognize and eliminate health disparities in ESRD patients.[331]

Closing the health equity gap would require multipronged approaches that effectively address the many drivers of health disparities. As summarized in the CY 2022 ESRD PPS final rule request for information, we noted our intention to initiate additional request(s) for information (RFIs) on closing the health equity gap, including identification of the most relevant social risk factors for people with ESRD (86 FR 61930). Advancing health equity would require a variety of efforts across the healthcare system. The reduction in healthcare disparities is one aspect of improving equity that we have prioritized. In the CY 2022 ESRD PPS final rule request for information, ''Closing the Health Equity Gap in CMS Hospital Quality Programs'' (86 FR 61928 through 61937), we described programs and policies we have implemented over the past decade with the aim of identifying and reducing healthcare disparities, including: the CMS Mapping Medicare Disparities Tool [332] and the CMS Disparity Methods stratified reporting.[333] CMS has also begun efforts supporting implementation of the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care (78 FR 58539); [334] as well as improvement of the collection of social determinants of health in standardized patient assessment data in four post-acute care settings and the collection of health-related social need data by model participants in the CMMI Accountable Health Communities Model.[335] [336] [337]

Measuring healthcare disparities and reporting these results to healthcare providers is a cornerstone of our approach to advancing healthcare equity. It is important to consistently measure differences in care received by different groups of our beneficiaries, and this can be achieved by methods to stratify quality measures. Measure stratification is defined for this purpose as calculating measure results for specific groups or subpopulations of patients. Assessing healthcare disparities through stratification is only one method for using healthcare quality measurement to address health equity, but it is an important approach that allows healthcare providers to tailor quality improvement initiatives, decrease disparity, track improvement over time, and identify opportunities to evaluate upstream drivers of health. The use of measure stratification to assess disparities has been identified by CMS Office of Minority Health (CMS OMH) as well as by external organizations such as the American Hospital Association as a critical component of an organized response to health disparities.[338] [339] To date, we have performed analyses of disparities in our quality programs by using a series of stratification methodologies identifying quality of care for patients with heightened social risk or with demographic characteristics with associations to poorer outcomes.

As efforts to improve methods and sources of social determinant and demographic data collection mentioned previously are ongoing, we would continue to evaluate opportunities to expand these current measure stratification reporting initiatives with existing sources of data. We aim to provide comprehensive and actionable information on health disparities to healthcare providers participating in our quality programs, in part, by starting with confidential reporting of stratified measure results that highlight potential gaps in care between groups of patients

[328] Centers for Medicare and Medicaid Services. (2016). CMS Quality Strategy. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Qualityinitiativesgeninfo/downloads/cms-quality-strategy.pdf.*

[329] *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[330] Centers for Medicare & Medicaid Services. (2022). Health Equity. Available at: *https://www.cms.gov/pillar/health-equity.*

[331] Centers for Medicare and Medicaid Services. (2016). CMS Quality Strategy. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Qualityinitiativesgeninfo/downloads/cms-quality-strategy.pdf.*

[332] Centers for Medicare and Medicaid Services. (2021). CMS Office of Minority Health. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH-Mapping-Medicare-Disparities.*

[333] Centers for Medicare and Medicaid Services. Disparity Methods Confidential Reporting. Available at: *https://qualitynet.cms.gov/inpatient/measures/disparity-methods.*

[334] *https://www.federalregister.gov/documents/2013/09/24/2013-23164/national-standards-for-culturally-and-linguistically-appropriate-services-clas-in-health-and-health.*

[335] Centers for Medicare and Medicaid Services. (2021). Accountable Health Communities Model. Available at: *https://innovation.cms.gov/innovation-models/ahcm.*

[336] *https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf.*

[337] Centers for Medicare and Medicaid Services. (2021). IMPACT Act Standardized Patient Assessment Data Elements. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/-IMPACT-Act-Standardized-Patient-Assessment-Data-Elements.*

[338] Centers for Medicare & Medicaid Services. (2021). Building an Organizational Response to Health Disparities [Fact Sheet]. U.S. Department of Health and Human Services. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Health-Disparities-Guide.pdf.*

[339] Improving Health Equity Through Data Collection and Use: A Guide for Hospital Leaders. (2011). Available at: *http://www.hpoe.org/Reports-HPOE/improvinghealthequity3.2011.pdf.*

using existing data sources. This includes examining and reporting disparities in care across additional social risk factors and demographic variables associated with historic disadvantage in the healthcare system, and examining disparities across additional healthcare quality measures, and in new care settings. As disparity measurement initiatives expand through the use of measure stratification, it is important to model efforts off of existing best practices by continuing to gather stakeholder feedback and to make use of lessons learned in the development of existing disparity reporting efforts.

Specific efforts aimed at closing the health equity gap in ESRD patients include the *Chronic Kidney Disease Disparities: Educational Guide for Primary Care,* which is intended to foster the development of primary care practice teams in order to enhance care for medically underserved patients with CKD and are at risk of progression of disease or complications,[340] and the CMS ETC Model, which aims to test the effectiveness of adjusting certain Medicare payments to encourage more home dialysis and kidney transplants, support beneficiary modality choice, and preserve or improve quality of care provided to ESRD beneficiaries while reducing Medicare expenditures.[341]

Measuring healthcare disparities and reporting the results to dialysis providers is under consideration as a central component of our approach to closing the health equity gap in patients with ESRD. Stratification of quality measures would facilitate consistent measurement of differences in care received and subsequent outcomes by different groups of patients. Stratification is one of several methodological approaches to estimating health disparities that would support facilities in tailoring quality improvement initiatives to reduce disparities and track improvement over time. We have identified stratification as a critical component of an organized response to health disparities.[342] [343] To date, we have employed stratification techniques in a few programs to evaluate quality of care for patients with disproportionate social risk burden and demographic characteristics associated with adverse health outcomes. For example, in the FY 2018 IPPS/LTCH PPS final rule, the Hospital Inpatient Quality Reporting Program introduced confidential reporting of hospital quality measure data stratified by dual eligibility (82 FR 38403 through 38409).

As efforts to improve methods and sources of social determinant and demographic data collection are ongoing, we intend to continue to evaluate opportunities to expand these current measure stratification reporting initiatives with existing sources of data. We anticipate expanding our efforts to provide comprehensive and actionable information on health disparities to dialysis providers participating in the ESRD QIP by providing measure stratification results to highlight potential gaps in care among patient groups. This includes examining and reporting disparities in care across specific social risk factors and demographic variables associated with historic disadvantage in ESRD care in particular and examining disparities across ESRD QIP measures. We aim to gather feedback from technical experts and dialysis providers as we evaluate existing best practices for measure stratification methods and reporting approaches applied to health disparity evaluation. As disparity measurement initiatives expand through the use of measure stratification, it is important to model efforts off of existing best practices by continuing to gather stakeholder feedback and to make use of lessons learned in the development of existing disparity reporting efforts.

There are several key considerations that we intend to consider when advancing the use of measurement and stratification as tools to address healthcare disparities and advance healthcare equity. We seek input on key considerations in five specific areas that could inform our approach. Each is described in more detail later in this section:

- *Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification in ESRD QIP*—This section identifies the approaches for measuring healthcare disparities through measure stratification in CMS quality reporting programs.
- *Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting*—This section describes considerations that could inform the selection of ESRD QIP measures to prioritize for stratification.
- *Principles for Social Risk Factor and Demographic Data Selection and Use*—This section describes social risk factor and demographic data that we would consider investigating for use in stratifying ESRD QIP measures for healthcare disparity measurement. Dialysis and other healthcare providers would use their own demographic data to address disparities affecting their patients.
- *Identification of Meaningful Performance Differences*—This section reviews several strategies for identifying meaningful differences in performance when ESRD QIP measures apply stratification or disparity reporting that are easily understood but remain useable by dialysis providers.
- *Guiding Principles for Reporting Disparity Results*—This final section reviews considerations we would take into account in determining how ESRD QIP would report disparity results to dialysis providers, as well as the ways different reporting strategies would hold providers accountable.

We would then solicit public input on these topics.

b. Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification in ESRD QIP

Our goal in developing methods to measure disparities in care is to provide actionable and useful results to dialysis providers. By quantifying healthcare disparities (that is, through quality measure stratification), we aim to provide useful tools for dialysis providers and facilities to drive improvements. We believe these results would support dialysis providers and facilities efforts in examining the underlying drivers of disparities in their patients' care and to develop their own innovative and targeted quality improvement interventions. With stratified disparity information available, it may be possible to drive system-wide advancement through incremental, provider-level improvement.

There are multiple conceptual approaches to stratifying measures for reporting health disparities. In recent years, we have focused on identifying healthcare disparities by reporting stratified results for acute care hospitals in two complementary ways. First, stratification by a given social risk factor or demographic variable has generated measure results for subgroups of patients cared for by individual providers that can be directly compared. This type of comparison identifies important disparities, such as gaps in care and outcomes between patient groups. This approach is sometimes referred to as ''within-provider'' disparity. This can be done for most

[340] CMS (2021). Chronic Kidney Disease Disparities: Educational Guide for Primary Care. Available at: *https://www.cms.gov/files/document/chronic-kidney-disease-disparities-educational-guide-primary-care.pdf.*

[341] CMS (2021). ESRD Treatment Choices (ETC) Model. Available at: *https://innovation.cms.gov/innovation-models/esrd-treatment-choices-model.*

[342] *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Health-Disparities-Guide.pdf.*

[343] *http://www.hpoe.org/Reports-HPOE/improvinghealthequity3.2011.pdf.*

measures that include patient-level data and can be helpful to quantitatively express a provider's disparity in care. However, similar to the measure itself, the approach to perform this type of comparison would differ based on the measure's complexity. For example, when risk adjustment is used in the measure, the stratification approach would have to be adapted to address clinical risk adjustment.[344] Second, a provider's performance on a measure for only the subgroup of patients with that social risk factor can be compared to other providers' performance for that same subgroup of patients (sometimes referred to as ''across-provider'' disparities measurement). This type of comparison illuminates the healthcare provider's performance for only the population with a given social risk factor, allowing comparisons for specific performance to be better understood and compared to peers or state and national benchmarks. These approaches are reviewed and recommended by The Assistant Secretary of Planning and Evaluation (ASPE) as ways to measure health equity in their 2020 Report to Congress.[345]

Alone, each approach may provide an incomplete picture of disparities in care for a particular measure, but when reported together with overall quality performance can give detailed information about where differences in care exist. For example, a dialysis provider may underperform when compared to national averages for patients with a given risk factor, but if they also underperform for patients without that risk factor, the measured difference, or disparity in care, could be negligible even though performance for the group historically underserved group remains poor. In this case, simply stratifying the measure results could show little difference in care between patient groups within the facility, comparing results for only the group that has been historically marginalized would signal the need to improve care for this population.

We are especially sensitive to the need to ensure all disparity reporting avoids measurement bias. Stratified results must be carefully examined for potential measurement or algorithmic bias that is introduced through stratified reporting.[346] Furthermore, results of stratified reporting must be evaluated for any type of selection bias that fails to capture disparity due inadequate representation of subgroups of patients in measure cohorts. During measure re-evaluation, we would aim to carefully examine stratified results and methods to mitigate the potential for drawing incorrect conclusion from results.

c. Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting

We intend to begin our efforts to provide stratified reporting for ESRD QIP measures, provided they offer meaningful and valid feedback to dialysis and other healthcare providers on their care for ESRD patients that may face social disadvantage or other forms of discrimination or bias. Further development of stratified reporting of ESRD QIP measures can provide dialysis and other healthcare providers with more granular results that support targeting resources and initiatives to improve health equity. We are mindful that it may not be possible to calculate stratified results for all ESRD QIP measures, or there may be situations where stratified reporting may not be desired. To help inform prioritization of the candidate ESRD QIP measures for stratified reporting, we aim to receive feedback on several systematic principles under consideration that we believe would help us prioritize measures for disparity reporting across programs.

These considerations, when assessed within the context of specific programs, like the ESRD QIP, help gauge the utility and potential uses of stratified measure results to provide usable and impactful information on disparity broadly across our programs. While we aim to standardize approaches where possible, we also recognize that the variety of measures and care settings involved and the contextual nature of stratified reporting would require decisions to be made at the program level.

We have developed the following guiding principles for prioritizing ESRD QIP measures for disparity reporting:

• *Prioritize validated clinical quality measures*—When considering disparity reporting of stratified quality measures, there are several advantages to focusing on recognized measures which have met industry standards for measure reliability and validity. First, existing measures highlight agreed upon priority areas for quality measurement specific to the program setting, which have been developed under adherence to the CMS Measures Management System Blueprint [347] and have been reviewed for their clinical and population relevance by experts knowledgeable about the nuances of care delivered in these settings. Furthermore, these measures have been reviewed for clinical significance, applicability, and scientific rigor by additional organizations, such as the National Quality Forum (NQF), and have been selected for inclusion in programs with their recommendations in mind. Adapting these existing tools to measure disparity through stratification maintains adherence to predefined measurement priorities and utilizes a great deal of extant expert and methodological validation. The application of stratified reporting to validated clinical quality measures which are used across the healthcare sector also aim to mitigate any potential additional administrative burden on healthcare providers, hospitals, and facilities.

• *Prioritizing Measures with Identified Disparity in Treatment or Outcomes Among Participating Facilities for Selected Social or Demographic Factors*—Candidate ESRD QIP measures for stratification should be supported by evidence of underlying healthcare disparities in the procedure, condition, or outcome being measured. A review of peer-reviewed research studies should be conducted to identify disparities related to treatment or procedure the measure evaluates, or outcome used to score the measure, and should carefully consider both social risk factors and patient demographics. Disparity related to the measure could be based on the outcome or procedures and practices assessed by the measure. In addition, analysis of Medicare-specific data should be done in order to demonstrate evidence of disparity in care for some or most healthcare providers that treat Medicare patients. In addition to disparities in outcomes and quality, consideration should also be given to conditions that have highly disproportionate prevalence in certain populations.

• *Prioritize Measures with Sufficient Sample Size to Allow for Reliable and Representative Comparisons*—Sample

[344] Centers for Medicare & Medicaid Services. (2015). Risk Adjustment Fact Sheet. Available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/Risk-Adjustment-Fact-Sheet.pdf.*

[345] ASPE. (2020). Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program: The Second of Two Reports Required by the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. Available at: *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//195191/Second-IMPACT-SES-Report-to-Congress.pdf.*

[346] Obermeyer Z., Powers B., Vogeli C., Mullainathan S. Dissecting racial bias in an algorithm used to manage the health of populations. Science. 2019;366(6464):447–53.

[347] Centers for Medicare and Medicaid Services. (2020). CMS Measures Management System Blueprint (Blueprint v 16.0).Available at: *https://www.cms.gov/Medicare/QualityInitiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.*

size holds specific significance for statistical calculations; however, it holds additional importance in the context of disparity reporting. Candidate measures for stratification would need to have sufficient sample size of enrollees to ensure that reported results of the disparity calculation are reliable and representative. This may be challenging if cohorts with a given social risk factor are small.

ESRD QIP may further consider measures for disparity reporting based on the utility of the stratified information, namely, prioritizing measures for stratification that show large differences in care between patient groups. Large differences in care for patients along social or demographic lines may indicate high potential that targeted initiatives could be effective. This is only one consideration in identifying the most meaningful differences in care, however, as initiatives designed for measures that show small disparities, but have very large cohorts, may have very large aggregate impacts on the national scale.

- *Prioritize Outcome Measures and Measures of Access and Appropriateness of Care*—Quality measurement in CMS programs often focus on outcomes of care, such as mortality or readmission, as high priority quality measures. For example, two key ESRD QIP outcome measures are the SHR clinical measure and the SRR clinical measure, which we are updating so that the measure results are expressed as rates. Such outcome measures remain a priority in the context of disparities measurement. However, measures that focus on access, when available, are also critical tools for addressing healthcare disparities. Measures that address healthcare access can counterbalance the risk of creating perverse incentives, for example, whereby a facility may improve its performance on existing quality measures by limiting access to care for populations who are historically underserved.

To complement measure stratification focused on clinical outcomes, the ESRD QIP would consider prioritizing measures with a focus on access to or appropriateness of care. These measures, when reported in tandem with clinical outcomes, would provide a broader picture of care provided at a facility, illuminate potential performance drivers, and identify organizations that fail to address access to care barriers for patient sub-groups. We acknowledge that the measurement of access and appropriateness of care is a growing field, and quality measures in these areas are limited. However, as our ability to measure these facets of healthcare improve, they would be high priority for measure stratification.

d. Principles for Social Risk Factor and Demographic Data Selection and Use

There are numerous non-clinical drivers of health associated with patient outcomes, including social risk factors such as socioeconomic status, housing availability, and nutrition, as well as marked inequity in outcomes based on patient demographics such as race and ethnicity, being a member of a minority religious group, geographic location, sexual orientation and gender identity, religion, and disability status.[348] [349] [350] [351] [352] [353] [354] [355] The World Health Organization (WHO) defines social risk factors as ''non-medical factors that influence health outcomes. They are the conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life.'' [356] These include factors such as income, education, job insecurity, food insecurity, housing, social inclusion and non-discrimination, access to affordable health services, and any others. Research has indicated that these social factors may have as much or more impact on health outcomes as clinical care itself.[357] [358] Additionally, differences in outcomes based on patient race and ethnicity have been identified as significant, persistent, and of high priority for CMS and other federal agencies.[359]

In prioritizing among social risk factors and demographic variables, disability, and other markers of disadvantage for stratified reporting, the ESRD QIP would develop approaches that have the most relevance for the existing measure set. Patient reported data are considered to be the gold standard for evaluating care for patients with social risk factors or who belong to certain demographic groups as this is the most accurate way to attribute social risk.[360] Although some of this information is currently reported on Form 2728—ESRD Medical Evidence Report Medicare Entitlement And/Or Patient Registration (OMB control number 0938–0046), we believe that additional development of patient-reported social risk factor and demographic variable data sources may be necessary to collect data that is complete enough to consider for disparity reporting. Currently, there are many efforts underway to further develop data collection for self-reported patient social risk and demographic variables. Yet, given that data sources are small, they may only have the ability to provide statistically significant disparity results for a small proportion of care facilities.

We would continue to evaluate patient-reported sources of social risk and demographic information. Until validated data are available, we are considering three sources of social risk and demographic data that would allow us to report stratified measure results:

[348] Joynt KE, Orav E, Jha AK (2011). Thirty-day readmission rates for Medicare beneficiaries by race and site of care. JAMA, 305(7):675–681.

[349] Lindenauer PK, Lagu T., Rothberg MB, et al. (2013). Income inequality and thirty-day outcomes after acute myocardial infarction, heart failure, and pneumonia: retrospective cohort study. British Medical Journal, 346.

[350] Trivedi AN, Nsa W, Hausmann LRM, et al. (2014). Quality and equity of care in U.S. hospitals. New England Journal of Medicine, 371(24):2298–2308.

[351] Polyakova, M, et al. (2021). Racial disparities in excess all-cause mortality during the early COVID–19 pandemic varied substantially across states. Health Affairs, 40(2): 307–316.

[352] Rural Health Research Gateway. (2018). Rural communities: Age, income, and health status. Rural Health Research Recap. Available at: *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-incomehealth-status-recap.pdf.*

[353] HHS Office of Minority Health (2020). 2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities. Available at: *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[354] Poteat TC, Reisner SL, Miller M, Wirtz AL (2020). COVID–19 vulnerability of transgender women with and without HIV infection in the Eastern and Southern U.S. medRxiv [Preprint]. 2020.07.21.20159327. doi: 10.1101/2020.07.21.20159327. PMID: 32743608; PMCID: PMC7386532.

[355] Milkie Vu et al. Predictors of Delayed Healthcare Seeking Among American Muslim Women, Journal of Women's Health 26(6) (2016) at 58; S.B. Nadimpalli, et al., The Association between Discrimination and the Health of Sikh Asian Indians.

[356] World Health Organization. Social Determinants of Health. Available at: *https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1.*

[357] Hood, C., Gennuso K., Swain G., Catlin B. (2016). County Health Rankings: Relationships Between Determinant Factors and Health Outcomes. Am J Prev Med. 50(2):129–135. doi:10.1016/j.amepre.2015.08.024.

[358] Chepaitis, A.E., Bernacet, A., Kordomenos, C., Greene, A.M., Walsh, E.G. (2020). Addressing social determinants of health in demonstrations under the financial alignment initiative. RTI International. Available at: *https://innovation.cms.gov/data-and-reports/2021/fai-sdoh-issue-brief.*

[359] White House. (2021). Executive Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. Available at: *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.*

[360] Jarrín OF, Nyandege AN, Grafova I B, Dong X., Lin H. (2020). Validity of race and ethnicity codes in Medicare administrative data compared with gold-standard self-reported race collected during routine home health care visits. Med Care, 58(1):e1–e8. doi: 10.1097/MLR.0000000000001216. PMID: 31688554; PMCID: PMC6904433.

• *Billing and Administrative Data*—The majority of quality measurement tools used in our quality programs focus on utilizing existing enrollment and claims data for Medicare beneficiaries. Using these existing data to assess disparity, for example by the use of dual enrollment for Medicare and Medicaid, allows for high impact analyses with negligible facility burden. There are, however, limitations in these data's usability for stratification analysis. Our current administrative race and ethnicity data have been shown to have historical inaccuracies due to limited collection classifications and attribution techniques, and are generally considered not to be accurate enough for stratification and disparity analyses.[361] International Classification of Diseases,10th Revision (ICD–10) codes for socioeconomic and psychosocial circumstances (''Z codes'' Z55 to Z65) represent an important opportunity to document patient-level social risk factors in Medicare beneficiaries, however, they are rarely used in clinical practice, limiting their usability in disparities measurement.[362] If the collection of social risk factor data improves in administrative data, we would continue to evaluate its applicability for stratified reporting in the future.

Dual eligibility is a widely used proxy for low socioeconomic status and is an exception to the previously discussed limitations, making it an effective indicator for worse outcomes due to low socioeconomic status. The use of dual eligibility in social risk factor analyses was supported by ASPE's First and Second Reports to Congress.[363] [364] These reports found that in the context of VBP programs, dual eligibility, as an indicator of social risk, was among the most powerful predictors of poor health outcomes among those social risk factors that ASPE examined and tested.

• *Area-based Indicators of Social Risk Information and Patient Demographics*—Area-based indicators pool area-level information to create approximations of patient risk or describe the neighborhood or context that a patient resides in. Popular among them are the use of the American Community Survey (ACS), which is commonly used to attribute social risk to populations at the ZIP code or Federal Information Processing Standards (FIPS) county level. Several indices, such as the Agency for Healthcare Research and Quality (AHRQ) Socioeconomic Status (SES) Index,[365] Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry Social Vulnerability Index (CDC/ATSDR SVI),[366] and Health Resources and Services Administration Area Deprivation Index,[367] combine multiple indicators of social risk into a single score which can be used to provide multifaceted contextual information about an area and may be considered as an efficient way to stratify measures that include many social risk factors.

• *Imputed Sources of Social Risk Information and Patient Demographics*—Imputed data sources use statistical techniques to estimate patient-reported factors, including race and ethnicity. In the case of race and ethnicity, indirect estimation improves upon imperfect and incomplete data by drawing on information about a person's name and address and the linkage of those variables to race and ethnicity. One such tool is the Medicare Bayesian Improved Surname Geocoding (MBISG) method (currently in version 2.1), which combines information from administrative data, surname, and residential location to estimate patient race and ethnicity.[368] This tool was originally developed by the RAND Corporation, and further customized for the Medicare population to improve existing CMS administrative data on race and ethnicity.

The MBISG 2.1 method does not assign a single race and ethnicity to an individual; instead, it generates a set of six probabilities, each estimating what the individual would self-identify as given a set of racial and ethnic groups to choose from including: American Indian or Alaska Native, Asian or Pacific Islander, Black, Hispanic, Multiracial, and White. In no case would the estimated probability be used for making inferences about a beneficiary; only self-reported data on race and ethnicity should be used for that purpose. However, in aggregate, these results can provide insight and accurate information at the population level, such as the patients of a given facility, or the members of a given plan. MBISG 2.1 is currently used by CMS' OMH to undertake various analyses, such as comparing scores on clinical quality of care measures from the Healthcare Effectiveness Database and Information Set (HEDIS) by race and ethnicity for Medicare Part C/D health plans, and in developing a Health Equity Summary Score (HESS) for Medicare Advantage (MA) health plans.[369]

While the use of area-based indicators and imputed data sources are not meant to replace efforts to improve patient-level data collection, we are considering how they might be used to quickly begin population-level disparity reporting of stratified measure results while being conscientious about data limitations.

Imputed data sources, particularly when used to identify patient populations for measurement, must be carefully evaluated for their potential to negatively affect the populations being studied. For this reason, imputed data sources should only be considered after significant validation study has been completed, including evaluation by key stakeholders for face validity, and any calculations that incorporate these

[361] Jarrín OF, Nyandege AN, Grafova IB., Dong X., Lin H. (2020). Validity of race and ethnicity codes in Medicare administrative data compared with gold-standard self-reported race collected during routine home health care visits. Med Care, 58(1):e1–e8. doi: 10.1097/MLR.0000000000001216. PMID: 31688554; PMCID: PMC6904433.

[362] Centers for Medicare & Medicaid Services, Office of Minority Health. (2021). Utilization of Z codes for social determinants of health among Medicare fee-for-service beneficiaries, 2019. Available at: *https://www.cms.gov/files/document/z-codes-data-highlight.pdf.*

[363] Office of the Assistant Secretary for Planning and Evaluation. (2016). Social risk factors and performance under Medicare's value-based purchasing programs. Available at: *https://aspe.hhs.gov/reports/report-congress-social-risk-factors-performance-under-medicares-value-based-purchasing-programs.*

[364] Office of the Assistant Secretary For Planning and Evaluation. (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Available at: *https://aspe.hhs.gov/reports/second-report-congress-social-risk-medicares-value-based-purchasing-programs.*

[365] Bonito A., Bann C., Eicheldinger C., Carpenter L. (2008). Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare & Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500–00–0024, Task No. 21) AHRQ Publication No. 08–0029–EF. Rockville, MD, Agency for Healthcare Research and Quality.

[366] Flanagan, B.E., Gregory, E.W., Hallisey, E.J., Heitgerd, J.L., Lewis, B. (2011). A social vulnerability index for disaster management. Journal of Homeland Security and Emergency Management, 8(1). Available at: *https://www.atsdr.cdc.gov/placeandhealth/svi/img/pdf/Flanagan_2011_SVIforDisasterManagement-508.pdf.*

[367] Center for Health Disparities Research. About the Neighborhood Atlas. Available at: *https://www.neighborhoodatlas.medicine.wisc.edu/.*

[368] Haas A., Elliott M.N., Dembosky J.W., Adams J.L., Wilson-Frederick S.M., Mallett J.S. et al. (2019). Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. Health Serv Res, 54(1):13–23. doi: 10.1111/1475–6773.13099. Epub 2018 Dec 3. PMID: 30506674; PMCID: PMC6338295. Available at: *https://pubmed.ncbi.nlm.nih.gov/30506674/.*

[369] Agniel D., Martino S.C., Burkhart Q., Hambarsoomian K., Orr N., Beckett M.K, et al. (2021). Incentivizing excellent care to at-risk groups with a health equity summary score. J Gen Intern Med, 36(7):1847–1857. doi: 10.1007/s11606–019–05473–x. Epub 2019 Nov 11. PMID: 31713030; PMCID: PMC8298664. Available at: *https://pubmed.ncbi.nlm.nih.gov/31713030/.*

methods should be continuously evaluated for the accuracy of their results and the necessity of their use. While neither imputed nor area-level geographic data should be considered a replacement for improved data collection, researchers have found their use to be a simple and cost-efficient way to make general estimations of social risk at a community level.[370] Even more potent, when patient-level information is not available, are the combination of several sources of imputed or area-level data to provide diverse perspectives on social risk of a population.

e. Identification of Meaningful Performance Differences

In examining potential ways to report disparity data in the ESRD QIP, including the results of quality measure stratification, we would consider different approaches to identifying meaningful differences in performance. Stratified results can be presented in a number of ways to describe to providers how well or poorly they are performing, or how they perform when compared to other care facilities. For this reason, it is important to identify how best to present meaningful differences in performance for measures of disparity reporting. We aim to provide information that offers meaningful information to dialysis providers. While we aim to use standardized approaches where possible, identifying differences in performance on stratified results would be made at the program level due to contextual variations across programs and settings. We look forward to feedback on the benefits and limitations of the possible reporting approaches we have described in this Request for Information.

- *Statistical Differences*—When aiming to examine differences in disparities results among facilities, the use of statistical testing can be helpful. There are many statistical approaches that can be used to reliably group results, such as using confidence intervals, creating cut points based on standard deviations, or using a clustering algorithm. Importantly, these approaches may result in groupings that are statistically different, but not meaningfully different depending on the distribution of results.
- *Rank Ordering and Percentiles*—Ordering healthcare providers in a ranked system is another option for reporting disparity results in a meaningful way. In this system, facilities could be ranked based on their performance on disparity measures to quickly allow them to compare their performance to other similar healthcare providers. This approach works well as a way for facilities to easily compare their own performance against others; however, a potential drawback is that it does not identify the overall magnitude of disparity. For example, if a measure shows large disparity in care for patients based on a given factor, and that degree of disparity has very little variation between healthcare providers, the difference between the top and bottom ranked facilities would be very small even if the overall disparity is large.
- *Threshold Approach*—A categorization system could also be considered for reporting disparity results. In this system, facilities could be grouped based on their performance using defined metrics, such as fixed intervals of results of disparity measures, indicating different levels of performance. Using a categorized system may be more easily understood by stakeholders by giving a clear indication that outcomes are not considered equal. However, this method does not convey the degree of disparity between facilities or the potential for improvement based on the performance of other facilities. Furthermore, it requires a determination of what is deemed 'acceptable disparity' when developing categories.
- *Benchmarking*—Benchmarking, or comparing individual results to, for example, state or national averages, is another potential reporting strategy. This type of approach could be done, especially in combination with a ranked or threshold approach, to give facilities more information about how they compare to the average care for a patient group.

Another consideration for each of these approaches is grouping similar care settings together for comparison through a peer grouping step, especially if a ranked system is used to compare facilities. Stakeholders have argued that comparisons between facilities have limited meaning if the facilities are not similar, and that peer grouping would improve their ability to interpret results. Overall, the value of peer grouping must be weighed against the potential to set different standards of meaningful disparity among different care settings.

f. Guiding Principles for Reporting Disparity Results

There are several options for reporting of disparity results to drive improvements in quality. Confidential reporting, or reporting results privately to providers, is an approach we have used for new newly adopted measures in a CMS quality program to give providers an opportunity to become more familiar with calculation methods and to begin improvement activities before other forms of reporting. Providing early results to facilities is an important way to provide facilities the information they need to design impactful strategies to reduce disparity. Public reporting, or reporting results publicly, is a second reporting option. This method could provide ESRD QIP participants and ESRD patients with important information on facility quality, and by turn relies on market forces to incentivize healthcare providers to improve and become more competitive in their markets without directly influencing payment from CMS. Payment accountability could potentially offer a direct line for us to reward healthcare providers for having low disparity rates, or for performing well for medically underserved population groups.

We are exploring the most optimal methods of reporting disparity results. Initially, confidential reporting may be prudent for facilities and healthcare providers to understand stratification methodology and the presentation of stratified results, and to begin to implement programs to reduce disparities at their facilities. We are considering this approach to begin having an impact on disparity, while allowing providers time to interpret results and set up processes to address disparities.

It would be important to carefully consider the context of reporting, including measure specifications, data sources, care setting, and dialysis providers' and patients' perspectives before implementing a reporting strategy. Earlier in this RFI, we identified risks to applying stratification to all measures using all available social risk factor and demographic variables, such as the chance that unexpected results may exacerbate disparity. We intend to consider these risks compared to the benefits of different reporting strategies when developing implementation plans.

Regardless of the methods used to report results, it is important to report stratified measure data alongside overall measure results. Review of both measure results along with stratified results can illuminate greater levels of detail about quality of care for subgroups of patients, providing important information to drive quality improvement. Unstratified quality measure results address general differences in quality of care between

[370] Bi, Q., He, F., Konty, K., Gould, L.H., Immerwahr, S., & Levanon Seligson, A. (2020). ZIP code-level estimates from a local health survey: Added value and limitations. Journal of Urban Health: Bulletin of the New York Academy of Medicine, 97(4), 561–567.

healthcare providers and promote improvement for all patients, but unless stratified results are available, it is unclear if there are subgroups of patients that benefit most from initiatives. Notably, even if overall quality measure scores improve, without identifying and measuring differences in outcomes between groups of patients, it is impossible to track progress in reducing disparity for patients with heightened risk of poor outcomes.

g. Solicitation of Public Comments

The goal of this request for information is to describe key considerations that we would acknowledge when advancing the use of measure stratification as one quality measurement tool to address healthcare disparities and advance health equity in the ESRD QIP. This is important as a means of setting priorities and expectations for the use of stratified measures. We specifically note that several important factors may limit the use of stratification or may need to be taken into consideration.

We invite general comments on the principles and approaches listed previously, or additional thoughts about disparity measurement or stratification guidelines suitable for overarching consideration across our programs. Specifically, we invite comment on:

- Overarching goals for measuring disparity that should be considered across CMS quality programs, including: the importance of pairing stratified results to evaluate gaps in care among groups of patients attributed to a given facility and comparison of care for a subgroup of patients across facilities, and the goal that these stratified results are reported alongside overall measure results to have a comprehensive view of disparities.
- Principles to consider for prioritization of measures for disparity reporting, including prioritizing stratification for: valid clinical quality measures; measures with established disparities in care; measures that have adequate sample size and representation among facilities; and, measures that consider access and appropriateness of care.
- Principles to be considered for the selection of social risk factors and demographic data for use measuring disparities, including the importance of identifying new social risk factor and demographic variables to use to stratify measures. We also seek comment on the use of imputed and area based social risk and demographic indicators for measure stratification when patient reported data are unavailable.
- Preferred ways that meaningful differences in disparity results can be identified or should be considered.
- Guiding principles for the use and application of the results of disparity measurement, such as providing confidential reporting initially versus public reporting.

V. End-Stage Renal Disease Treatment Choices (ETC) Model

A. Background

Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and CHIP expenditures while preserving or enhancing the quality of care furnished to such programs' beneficiaries. The purpose of the ETC Model is to test the effectiveness of adjusting certain Medicare payments to ESRD facilities and Managing Clinicians to encourage greater utilization of home dialysis and kidney transplantation, support beneficiary modality choice, reduce Medicare expenditures, and preserve or enhance the quality of care. As described in the Specialty Care Models final rule (85 FR 61114), beneficiaries with ESRD are among the most medically fragile and high-cost populations served by the Medicare program. ESRD Beneficiaries require dialysis or kidney transplantation to survive, and the majority of ESRD beneficiaries receiving dialysis receive hemodialysis in an ESRD facility. However, as described in the Specialty Care Models final rule, alternative renal replacement modalities to in-center hemodialysis, including home dialysis and kidney transplantation, are associated with improved clinical outcomes, better quality of life, and lower costs than in-center hemodialysis (85 FR 61264).

The ETC Model is a mandatory payment model. ESRD facilities and Managing Clinicians are selected as ETC Participants based on their location in Selected Geographic Areas—a set of 30 percent of Hospital Referral Regions (HRRs) that have been randomly selected to be included in the ETC Model, as well as HRRs with at least 20 percent of ZIP codes™ located in Maryland.[371] CMS excludes all U.S. Territories from the Selected Geographic Areas.

Under the ETC Model, ETC Participants are subject to two payment adjustments. The first is the Home Dialysis Payment Adjustment (HDPA), which is an upward adjustment on certain payments made to participating ESRD facilities under the ESRD Prospective Payment System (PPS) on home dialysis claims, and an upward adjustment to the Monthly Capitation Payment (MCP) paid to participating Managing Clinicians on home dialysis-related claims. The HDPA applies to claims with claim service dates beginning January 1, 2021, and ending December 31, 2023.

The second payment adjustment under the ETC Model is the PPA. For the PPA, we assess ETC Participants' home dialysis rates and transplant rates during a Measurement Year (MY), which includes 12 months of performance data. Each MY has a corresponding PPA Period—a 6-month period that begins 6 months after the conclusion of the MY. We adjust certain payments for ETC Participants during the PPA Period based on the ETC Participant's home dialysis rate and transplant rate, calculated as the sum of the transplant waitlist rate and the living donor transplant rate, during the corresponding MY.

Based on an ETC Participant's achievement in relation to benchmarks based on the home dialysis rate and transplant rate observed in Comparison Geographic Areas during the Benchmark Year, and the ETC Participant's improvement in relation to their own home dialysis rate and transplant rate during the Benchmark Year, we will make an upward or downward adjustment to certain payments to the ETC participant. The magnitude of the positive and negative PPAs for ETC Participants increases over the course of the Model. These PPAs apply to claims with claim service dates beginning July 1, 2022, and ending June 30, 2027.

In the CY 2022 ESRD PPS final rule, we finalized a number of changes to the ETC Model. We made adjustments to the calculation of the home dialysis rate (86 FR 61951 through 61955) and the transplant rate (86 FR 61955 through 61959), and updated the methodology for attributing Pre-emptive Living Donor Transplant (LDT) Beneficiaries (86 FR 61950 through 61951). We modified the achievement benchmarking and scoring methodology (86 FR 61959 through 61968), as well as the improvement benchmarking and scoring methodology (86 FR 61968 through 61971). We specified the method and requirements for sharing performance data with ETC Participants (86 FR 61971 through 61984). We also made a number of updates and clarifications to the kidney disease patient education services waivers and made certain related flexibilities available to ETC Participants (86 FR 61984 through 61994).

[371] ZIP code™ is a trademark of the United States Postal Service.

B. Proposed Updates to the ETC Model

1. Performance Payment Adjustment Achievement Scoring Methodology

Under the ETC Model, the PPA is a positive or negative adjustment on dialysis and dialysis-related Medicare payments for both home dialysis and in-center dialysis. To calculate an ETC Participant's PPA, we assess the ETC Participant's performance on the home dialysis rate and the transplant rate in relation to achievement and improvement benchmarks, as described in 42 CFR 512.370(b) and (c), respectively.

An ETC Participant's achievement is scored at the aggregation group level in relation to achievement benchmarks, which are constructed based on the home dialysis rate and transplant rate observed among aggregation groups located in Comparison Geographic Areas during corresponding Benchmark Years. Achievement benchmarks are percentile based, and set at the <30th, ≥30th, ≥50th, ≥75th, and ≥90th percentile of rates for Comparison Geographic Areas during the Benchmark Year. An ETC Participant receives the achievement points that that correspond with its performance, at the aggregation group level, on the home dialysis rate and transplant rate in relation to the achievement benchmarks, as described in § 512.370(b)(1).

In the CY 2022 ESRD PPS final rule, we modified the achievement benchmarking methodology such that, beginning MY3, achievement benchmarks are stratified based on the proportion of beneficiary years attributed to the ETC Participant's aggregation group for which attributed beneficiaries are dually eligible for Medicare and Medicaid or receive the Low Income Subsidy (LIS). Beginning MY3, we create two strata, with the cutpoint set at 50 percent of attributed beneficiary years being for attributed beneficiaries who were dual-eligible or received the LIS, as described in § 512.370(b)(2).

Based on subsequent analysis, we have found that stratifying achievement benchmarks in this way has increased the likelihood that the lowest benchmark—set at the 30th percentile—could be set at a home dialysis rate or transplant rate of zero. This change occurred because dividing the set of attributable beneficiaries in Comparison Geographic Areas into two strata means that there are fewer observations per strata, changing the underlying distributions.

Awarding achievement points for a home dialysis rate or transplant rate of zero is inconsistent with the design and goals of the ETC Model. The purpose of the ETC Model is to test the use of certain payment adjustments to increase rates of home dialysis and transplantation, thereby improving or maintaining quality and reducing Medicare expenditures. Awarding achievement points, which are used to determine the magnitude and direction of an ETC Participant's PPA, for a home dialysis rate or a transplant rate of zero is antithetical to the ETC Model's design.

To address this issue, we propose to further modify the achievement scoring methodology for the ETC Model. Specifically, we propose to add a requirement, to be codified in a new provision at § 512.370(b)(3), to specify that, beginning MY5, an ETC Participant's aggregation group must have a home dialysis rate or a transplant rate greater than zero to receive an achievement score for that rate. We seek comment on this proposal.

2. Kidney Disease Patient Education Services

Under section 1861(ggg)(1) of the Act and § 410.48 of our regulations, Medicare Part B covers outpatient, face-to-face kidney disease patient education services provided by certain qualified persons to beneficiaries with Stage IV chronic kidney disease. As noted in the Specialty Care Models final rule, kidney disease patient education services play an important role in educating patients about their kidney disease and helping them make informed decisions on the appropriate type of care and/or dialysis needed for them (85 FR 61337). In addition, as we noted in the Specialty Care Models final rule, kidney disease patient education services are designed to educate and inform beneficiaries about the effects of kidney disease, their options for transplantation, dialysis modalities, and vascular access (85 FR 61337).

Because kidney disease patient education services have been infrequently billed, we found it necessary for purposes of testing the ETC Model to waive select requirements of kidney disease patient education services as authorized in section 1861(ggg)(1) of the Act and in the implementing regulation at 42 CFR 410.48. Specifically, to broaden the availability of kidney disease patient education services under the ETC Model, we used our authority under section 1115A(d) of the Act to waive certain requirements for individuals and entities that furnish and bill for kidney disease patient education services. We codified these waivers at § 512.397(b). These include waivers to allow a broader scope of beneficiaries to have access to kidney disease patient education services, as well as greater flexibility in how the kidney disease patient education services are performed. CMS also waived the requirement that only doctors, physician assistants, nurse practitioners, and clinical nurse specialists can furnish kidney disease patient education services to allow kidney disease patient education services to be provided by clinical staff under the direction of and incident to the services of the Managing Clinician who is an ETC Participant.

Specifically, under § 512.397(b)(1), kidney disease patient education services may be provided by ''qualified staff,'' which includes any qualified person (as defined at § 410.48(a)) as well as clinical staff. In the CY 2022 ESRD PPS final rule (86 FR 61988), we defined ''clinical staff'' under 42 CFR 512.310 of our regulations to mean a licensed social worker or registered dietician/nutrition professional who furnishes services for which payment may be made under the physician fee schedule under the direction of and incident to the services of the Managing Clinician who is an ETC Participant.

In addition, in the CY 2022 ESRD PPS final rule, we added a new provision at § 512.397(c) permitting an ETC Participant to reduce or waive the 20 percent coinsurance requirement for kidney disease patient education services furnished on or after January 1, 2022, if several conditions are satisfied, including a requirement that the individual or entity that furnished the services is qualified staff and was not leased from or otherwise provided by an ESRD facility or related entity. We finalized this cost-sharing reduction policy because we believed this patient incentive would advance the ETC Model's goal of increasing access to kidney disease patient education services and make beneficiaries more aware of their choices in kidney treatment, including the choice of receiving home dialysis, self-dialysis, or nocturnal in-center dialysis, rather than traditional in-center dialysis. We also determined that under § 512.397(c)(3), the federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)) is available to protect the kidney disease patient education coinsurance waivers that satisfy the requirements of such safe harbor and § 512.397(c)(1).

We recognized in the CY 2022 ESRD PPS final rule that ESRD facilities and other entities sometimes enter into arrangements with clinicians or other

parties to provide certain services (86 FR 61991). We also recognized that some ETC Participants may wish to furnish kidney disease patient education services using staff or other resources furnished under a contractual arrangement with an ESRD facility or other entity. We were concerned, however, that even if such arrangements were structured to comply with all applicable fraud and abuse laws, they could nevertheless result in program abuse. Specifically, such arrangements could operate to circumvent the statutory prohibition against ESRD facilities furnishing kidney disease patient education services. For example, the staff or resources furnished to the ETC Participant from an ESRD facility or related entity could be used to market a specific ESRD facility or chain of ESRD facilities to beneficiaries who may need to choose an ESRD facility in the future. We stated that we did not believe that ETC Participants should obtain safe harbor protection for the reduction or waiver of cost-sharing on kidney disease patient education services if such services were furnished by personnel leased from an ESRD facility or related entity. We explained that a ''related entity'' would include any entity that is directly or indirectly owned in whole or in part by an ESRD facility and that this policy aligns with the statutory provision that excludes ESRD facilities from the individuals and entities that can furnish kidney disease patient education services.

Currently, the prohibition against the furnishing of kidney disease patient education services by qualified staff who are leased from or otherwise provided by an ESRD facility or related entity does not apply unless an ETC Participant reduces or waives the beneficiary's coinsurance obligation for kidney disease patient education services. We propose that a similar prohibition would apply with respect to ''clinical staff'' regardless of whether the ETC Participant is reducing or waiving the kidney disease patient education coinsurance obligation. Specifically, we are proposing to add a sentence to § 512.397(b)(1) stating that, for purposes of the waiver under § 512.397(b)(1) of our regulations, beginning for MY5, ''clinical staff'' may not be leased from or otherwise provided to the ETC Participant by an ESRD facility or related entity. Applying this prohibition on ''clinical staff'' could also protect beneficiaries and their care choices, and limit the likelihood that the ''clinical staff'' furnished to the ETC Participant from an ESRD facility or related entity would result in steering a beneficiary to a specific ESRD facility or chain of ESRD facilities.

To further ensure that beneficiaries are not unduly influenced to choose a particular ESRD facility, we are also considering whether the final rule should include a requirement that, for purposes of the waiver under§ 512.397(b)(1), the content of the kidney disease patient education furnished by clinical staff cannot market a specific ESRD facility or chain of ESRD facilities to beneficiaries. However, we recognize that some forms of marketing can be quite subtle. For example, a beneficiary's treatment choices could be unduly biased if the beneficiary is made aware of the leased staff person's employment by an ESRD facility (for example, by the trainer's responses to beneficiary questions or discussion of personal experience, or even by a logo on the trainer's clothing or educational materials). Because it would be difficult for us to enforce this content restriction in many cases of subtle marketing, we do not think this restriction would sufficiently protect against improper influence of beneficiary choice with respect to the selection of an ESRD facility unless we also finalize our proposal to prohibit qualified staff from furnishing kidney disease patient education services if they are leased from or otherwise provided by an ESRD facility.

We solicit public comments on these proposed changes to § 512.397(b)(1).

3. Publication of Participant Performance

In the Specialty Care Models final rule, CMS established certain general provisions in subpart A of 42 CFR part 512 that apply to the ETC Model. One such general provision pertains to rights in data. Specifically, in the Specialty Care Models final rule, we stated that in order to enable CMS to evaluate the Innovation Center models (defined to include the ETC Model and Radiation Oncology Model) as required by section 1115A(b)(4) of the Act and to monitor the Innovation Center models pursuant to § 512.150, in § 512.140(a) we would use any data obtained in accordance with §§ 512.130 and 512.135 to evaluate and monitor the Innovation Center models (85 FR 61124). We also stated that, consistent with section 1115A(b)(4)(B) of the Act, CMS would disseminate quantitative and qualitative results and successful care management techniques, including factors associated with performance, to other providers and suppliers and to the public. We stated that the data to be disseminated would include, but would not be limited to, patient de-identified results of patient experience of care and quality of life surveys, as well as patient de-identified measure results calculated based upon claims, medical records, and other data sources. We finalized these policies in 42 CFR 512.140(a).

Consistent with these provisions, we intend to publish patient de-identified results from all MYs of the ETC Model, including results from MYs that have already been completed. Specifically, for each MY, we intend to post the aggregate results for the home dialysis rate and the transplant rate for each aggregation group, as well as the individual components of each rate for the aggregation group as a whole. This would include the number of beneficiary months in home dialysis, self-dialysis, or nocturnal dialysis and the number of beneficiary months on the transplant waitlist, as well as the number of living donor transplants and, if applicable, pre-emptive living donor transplants performed. We would also identify all of the ESRD facilities or Managing Clinicians in the aggregation group for the MY. The results would be published on the ETC Model website. Given that the ETC Model includes a process for ETC Participants to request a targeted review of the calculation of the modality performance score (MPS)—which is calculated based on the various rates we intend to publish—CMS intends to publish these rates only after they have been finalized and CMS has resolved any targeted review requests timely received from ETC Participants under 42 CFR 512.390(c). We believe that the release of this information would inform the public about the cost and quality of care and about ETC Participants' performance in the ETC Model. This would supplement the annual evaluation reports that CMS is required to conduct and release to the public under section 1115A(b)(4) of the Act.

We seek comment on our intent to post this information to our website, as well as the information we intend to post and the manner and timing of the posting.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork

Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

1. ESRD QIP—Wage Estimates (OMB Control Numbers 0938–1289 and 0938–1340)

To derive wages estimates, we used data from the U.S. Bureau of Labor Statistics' May 2020 National Occupational Employment and Wage Estimates. In the CY 2016 ESRD PPS final rule (80 FR 69069), we stated that it was reasonable to assume that Medical Records and Health Information Technicians, who are responsible for organizing and managing health information data, are the individuals tasked with submitting measure data to CROWNWeb (now EQRS) and NHSN, as well as compiling and submitting patient records for the purpose of data validation studies. The most recently available median hourly wage of a Medical Records and Health Information Technician is $21.20 per hour.[372] We also calculate fringe benefit and overhead at 100 percent. We adjusted these employee hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance on estimating the cost of fringe benefits and overhead. We stated that these are necessarily rough adjustments, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, we stated that there is no practical alternative and we believe that these are reasonable estimation methods. Therefore, using these assumptions, we estimated an hourly labor cost of $42.40 as the basis of the wage estimates for all collections of information calculations in the ESRD QIP.

We used this updated wage estimate, along with updated facility and patient counts to re-estimate the total information collection burden in the ESRD QIP for PY 2025 that we discussed in the CY 2022 ESRD QIP final rule (86 FR 61998 through 61999) and to estimate the total information collection burden in the ESRD QIP for PY 2026. We provide the re-estimated information collection burden associated with the PY 2025 ESRD QIP and the newly estimated information collection burden associated with the PY 2026 ESRD QIP in section VII.C.3 of this proposed rule. Although we are also proposing updates for PY 2023 and PY 2024, these proposals would not affect our estimates of the annual burden associated with the program's information collection requirements, and therefore we are not updating our previously finalized information collection burdens associated with the PY 2023 or PY 2024 ESRD QIP in this proposed rule.

2. Estimated Burden Associated With the Data Validation Requirements for PY 2025 and PY 2026 (OMB Control Numbers 0938–1289 and 0938–1340)

In the CY 2020 ESRD PPS final rule, we finalized a policy to adopt the CROWNWeb data validation methodology that we previously adopted for the PY 2016 ESRD QIP as the methodology we would use to validate CROWNWeb data for all payment years, beginning with PY 2021 (83 FR 57001 through 57002). Although we are now using EQRS to report data that was previously reported in CROWNWeb, the data validation methodology remains the same. Under this methodology, 300 facilities are selected each year to submit 10 records to CMS, and we reimburse these facilities for the costs associated with copying and mailing the requested records. The burden associated with these validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. In this proposed rule, we are not proposing any changes to the EQRS data validation process, however, we are updating these burden estimates using a newly available wage estimate of a Medical Records and Health Information Technician. In the CY 2020 ESRD PPS final rule, we estimated that it would take each facility approximately 2.5 hours to comply with this requirement (84 FR 60787). If 300 facilities are requested to submit records, we estimated that the total combined annual burden for these facilities would be 750 hours (300 facilities × 2.5 hours). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff would submit these data, we estimate that the aggregate cost of the EQRS data validation each year would be approximately $31,800 (750 hours × $42.40), or an annual total of approximately $106.00 ($31,800/300 facilities) per facility in the sample. The burden cost increase associated with these requirements would be revised in the information collection request (OMB control number 0938–1289).

In the CY 2021 ESRD PPS final rule, we finalized our policy to reduce the number of records that a facility selected to participate in the NHSN data validation must submit to a CMS contractor, beginning with PY 2023 (85 FR 71471 through 71472). Under this finalized policy, a facility is required to submit records for 20 patients across any two quarters of the year, instead of 20 records for each of the first two quarters of the year. The burden associated with this policy is the time and effort necessary to submit the requested records to a CMS contractor. In this proposed rule, we are not proposing any changes to the NHSN data validation process, however, we are updating these burden estimates using a newly available wage estimate of a Medical Records and Health Information Technician. Applying our policy to reduce the number of records required from each facility participating in the NHSN validation, we estimated that it would take each facility approximately 5 hours to comply with this requirement. If 300 facilities are requested to submit records each year, we estimated that the total combined annual burden hours for these facilities per year would be 1,500 hours (300 facilities × 5 hours). Since we anticipate that Medical Records and Health Information Technicians or similar staff would submit these data, using the newly available wage estimate of a Medical Records and Health Information Technician, we estimate that the aggregate cost of the NHSN data validation each year would be approximately $63,600 (1,500 hours × $42.40), or a total of approximately $212 ($63,600/300 facilities) per facility in the sample. While the burden hours estimate would not change, the burden cost updates associated with these requirements would be revised in the information collection request (OMB control number 0938–1340).

3. EQRS Reporting Requirements for PY 2023 and PY 2024 (OMB Control Number 0938–1289)

To determine the burden associated with the EQRS reporting requirements (previously known as the CROWNWeb reporting requirements), we look at the

[372] *https://www.bls.gov/oes/current/oes292098.htm.* Accessed on June 7, 2021.

total number of patients nationally, the number of data elements per patient-year that the facility would be required to submit to EQRS for each measure, the amount of time required for data entry, the estimated wage plus benefits applicable to the individuals within facilities who are most likely to be entering data into EQRS, and the number of facilities submitting data to EQRS. In the CY 2021 ESRD PPS final rule, we estimated that the burden associated with EQRS reporting requirements for the PY 2023 ESRD QIP was approximately $208 million (85 FR 71475).

As discussed in section IV.B.2 of this proposed rule, we are proposing six measure suppressions that would apply for PY 2023. However, we believe that these proposals would not affect our estimates of the annual burden associated with the Program's information collection requirements, as facilities are still expected to continue to collect measure data during this time period. Although we are updating the SHR and SRR clinical measure results to be expressed as rates beginning in PY 2024 in section IV.D of this proposed rule, these technical updates would not affect our estimates of the annual burden associated with the Program's information collection requirements.

4. EQRS Reporting Requirements for PY 2025 and PY 2026 (OMB Control Number 0938–1289)

To determine the burden associated with the EQRS reporting requirements (previously known as the CROWNWeb reporting requirements), we look at the total number of patients nationally, the number of data elements per patient-year that the facility would be required to submit to EQRS for each measure, the amount of time required for data entry, the estimated wage plus benefits applicable to the individuals within facilities who are most likely to be entering data into EQRS, and the number of facilities submitting data to EQRS. In the CY 2022 ESRD PPS final rule, we estimated that the burden associated with EQRS reporting requirements for the PY 2025 ESRD QIP was approximately $215 million for approximately 5,085,050 total burden hours (86 FR 61999).

We are not proposing any changes in this proposed rule that would affect the burden associated with EQRS reporting requirements for PY 2025 or PY 2026. However, we have re-calculated the burden estimate for PY 2025 using updated estimates of the total number of ESRD facilities, the total number of patients nationally, and wages for Medical Records and Health Information Technicians or similar staff as well as a refined estimate of the number of hours needed to complete data entry for EQRS reporting. Consistent with our approach in the CY 2022 ESRD PPS final rule (86 FR 61999), in this proposed rule we are estimating that the amount of time required to submit measure data to EQRS is 2.5 minutes per element and are not using a rounded estimate of the time needed to complete data entry for EQRS reporting. There are 229 data elements for 532,931 patients across 7,717 facilities. At 2.5 minutes per element, this yields approximately 658.94 hours per facility. Therefore, the PY 2025 burden is 5,085,050 hours (658.94 hours $\times$ 7,717 facilities). Using the wage estimate of a Medical Records and Health Information Technician, we estimate that the PY 2025 total burden cost is approximately $215 million (5,085,050 hours $\times$ $42.40). Although the burden hours and associated burden cost in this proposed rule are the same as we previously finalized in the CY 2022 ESRD PPS final rule (86 FR 61999), we will update these numbers in the final rule if necessary. There is no net incremental burden change from PY 2025 to PY 2026 because we are not changing the reporting requirements for PY 2026.

5. Additional Reporting Requirements Beginning With PY 2025

In section IV.E.1.a of the preamble of this proposed rule, we are proposing to adopt a COVID–19 HCP Vaccination reporting measure beginning with the PY 2025 ESRD QIP. Facilities would submit data through the CDC NHSN. The NHSN is a secure, internet-based system maintained by the CDC and provided free. Currently, the CDC does not estimate burden for COVID–19 vaccination reporting under the CDC information collection requirement (ICR) approved under OMB control number 0920–1317 because the agency has been granted a waiver under section 321 of the National Childhood Vaccine Injury Act (NCVIA).[373] Although the burden associated with the COVID–19 HCP Vaccination reporting measure is not accounted for under the CDC ICR 0920–1317 or 0920–0666 due to the NCVIA waiver, the estimated cost and burden information are included in section VII.D.2.b and would be accounted for by the CDC under OMB control number 0920–1317.

If you comment on these information collection, that is, reporting, recordkeeping, or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received on/by August 29, 2022.

VII. Regulatory Impact Analysis

A. Statement of Need

1. ESRD PPS

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This rule proposes several routine updates and policy changes to the ESRD PPS for CY 2023. The proposed routine updates include the CY 2023 wage index values, the wage index budget-neutrality adjustment factor, the outlier payment threshold amounts, and the TPNIES offset amount. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2023 for renal dialysis services furnished to ESRD beneficiaries.

This rule also proposes a number of changes to improve payment stability and adequacy under the ESRD PPS. As discussed in section II.B.1.a.(1) of this proposed rule, we are proposing to rebase and revise the ESRDB market basket to reflect a CY 2020 base year. We are also proposing to increase the ESRD PPS wage index floor as discussed in section II.B.1.b.(3) of this proposed rule, and to apply a permanent 5-percent cap on wage index decreases for CY 2023 and subsequent years, as discussed in section II.B.1.b.(2) of this proposed rule. Lastly, as discussed in section II.B.1.c.(4) of this proposed rule, we are proposing to change our

[373] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

methodology for calculating the FDL amount for adults in order to target more effectively ESRD PPS outlier payments that equal 1 percent of total ESRD PPS payments. We believe that each of these proposed changes would improve payment stability and adequacy under the ESRD PPS.

Furthermore, as discussed in section II.B.1.f. of this proposed rule, we are proposing to modify the definition of ''oral-only drug'' at § 413.234(a) to specify that equivalence refers to functional equivalence, in line with our current drug designation process and reliance on the ESRD PPS functional categories. We believe this proposal would improve beneficiaries' access to renal dialysis drugs, promote health equity, and advance other goals as discussed in the proposal. Lastly, we are proposing to clarify the descriptions of several existing ESRD PPS functional categories to ensure our descriptions are as clear as possible for potential TDAPA applicants and the public. We believe this proposed clarification would improve public understanding of the ESRD PPS functional categories and drug designation process.

2. AKI

This rule proposes routine updates to the payment for renal dialysis services furnished by ESRD facilities to individuals with AKI. As discussed in section III.B.2 of this proposed rule, we are also proposing to apply to all AKI dialysis payments in an ESRD facility the same wage index floor and permanent 5-percent cap on wage index decreases that we are proposing to apply under the ESRD PPS. We believe that these proposed changes would improve payment stability and adequacy for AKI dialysis in ESRD facilities. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2023 for renal dialysis services furnished to patients with AKI in accordance with section 1834(r) of the Act.

3. ESRD QIP

Section 1881(h)(1) of the Act requires a payment reduction of up to 2 percent for eligible facilities that do not meet or exceed the mTPS established with respect to performance standards for the ESRD QIP each year. This proposed rule proposes updates for the ESRD QIP, including the proposed suppression of several ESRD QIP measures for PY 2023 under our previously finalized measure suppression policy, a proposed update to the PY 2023 performance standards, updates regarding the SHR clinical measure and the SRR clinical measure for PY 2024, and proposed updates regarding the STrR and Hypercalcemia measures, the proposed adoption of the COVID–19 HCP Vaccination reporting measure, as well as a proposal to create a new reporting measure domain and to re-weight current measure domains, beginning in PY 2025.

4. ETC Model

As described in detail in section V of this proposed rule, we believe it is necessary to propose certain changes to the ETC Model. Under the proposed changes to the ETC Model, ETC Participants would continue to receive adjusted payments but beginning MY5, certain aspects of the ETC Model used to determine those payment adjustments would change. The proposed change to the PPA achievement scoring methodology is necessary to increase fairness and accuracy of the PPA. The proposed change to the kidney disease patient education services waiver and the discussion of our intent to disseminate participant-level model performance information to the public are necessary to support ETC Participants operating in the ETC Model.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2))

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with economically significant effects ($100 million or more in any 1 year). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''economically significant'' as measured by the $100 million threshold. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. We solicit comments on the regulatory impact analysis provided.

C. Impact Analysis

1. ESRD PPS

We estimate that the proposed revisions to the ESRD PPS would result in an increase of approximately $320 million in payments to ESRD facilities in CY 2023, which includes the amount associated with proposed updates to the outlier thresholds, proposed payment rate update, proposed updates to the wage index, and continuation of the approved TPNIES from CY 2022.

2. AKI

We estimate that the proposed updates to the AKI payment rate would result in an increase of approximately $2 million in payments to ESRD facilities in CY 2023.

3. ESRD QIP

We estimate that the proposed updates to the ESRD QIP will result in an additional $37 million in estimated payment reductions across all facilities for PY 2025.

4. ETC Model

We estimate that the proposed changes to the ETC Model would not impact the Model's projected direct savings from payment adjustments alone. We estimate that the Model would generate $28 million in direct savings related to payment adjustments over 6.5 years.

D. Detailed Economic Analysis

In this section, we discuss the anticipated benefits, costs, and transfers associated with the changes proposed in

this proposed rule. Additionally, we estimate the total regulatory review costs associated with reading and interpreting this proposed rule.

1. Benefits

Under the proposed CY 2023 ESRD PPS and AKI payment, ESRD facilities would continue to receive payment for renal dialysis services furnished to Medicare beneficiaries under a case-mix adjusted PPS. We continue to expect that making prospective payments to ESRD facilities would enhance the efficiency of the Medicare program. Additionally, we expect that updating ESRD PPS and AKI payments by 2.4 percent based on the proposed CY 2023 ESRD PPS market basket update less the proposed CY 2023 productivity adjustment would improve or maintain beneficiary access to high quality care by ensuring that payment rates reflect the best available data on the resources involved in delivering renal dialysis services.

2. Costs

a. ESRD PPS and AKI

We do not anticipate the provisions of this proposed rule regarding ESRD PPS and AKI rates-setting would create additional cost or burden to ESRD facilities.

b. ESRD QIP

As discussed in section IV.B.2 of this proposed rule, we are proposing measure suppressions that would apply for PY 2023. However, we believe that none of the policies that we are proposing in this proposed rule would affect our estimates of the annual burden associated with the Program's information collection requirements, as facilities are still expected to continue to collect measure data during this time period. For PY 2025 and PY 2026, we have re-estimated the costs associated with the information collection requirements under the ESRD QIP with updated estimates of the total number of ESRD facilities, the total number of patients nationally, wages for Medical Records and Health Information Technicians or similar staff, and a refined estimate of the number of hours needed to complete data entry for EQRS reporting. We have made no changes to our methodology for calculating the annual burden associated with the information collection requirements for the EQRS validation study (previously known as the CROWNWeb validation study), the NHSN validation study, and EQRS reporting.

In section IV.E.1.a of the preamble of this proposed rule, we are proposing to adopt a COVID–19 HCP Vaccination reporting measure beginning in PY 2025. Facilities would submit data through the CDC NHSN. The NHSN is a secure, internet-based system maintained by the CDC and provided free. Currently, the CDC does not estimate burden for COVID–19 vaccination reporting under the CDC PRA package approved under OMB control number 0920–1317 because the agency has been granted a waiver under section 321 of the National Childhood Vaccine Injury Act (NCVIA).[374]

We estimate that it would take each facility, on average, approximately 1 hour per month to collect data for the COVID–19 HCP Vaccination reporting measure and enter it into NHSN. We have estimated the time to complete this entire activity, since it could vary based on provider systems and staff availability. This burden is comprised of administrative hours and wages. We believe it would take an Administrative Assistant [375] between 45 minutes and 1 hour and 15 minutes to enter this data into NHSN. For PY 2025 and subsequent years, facilities would incur an additional annual burden between 9 hours (0.75 hours/month × 12 months) and 15 hours (1.25 hours/month × 12 months) per facility and between 69,453 hours (9 hours/facility × 7,717 facilities) and 115,755 hours (15 hours/facility × 7,717 facilities) for all facilities. Each facility would incur an estimated cost of between $329.58 (9 hours × $36.62/hour) and $549.30 annually (15 hours × $36.62/hour). The estimated cost across all facilities would be between $2,543,368.86 ($329.58/facility × 7,717 facilities) and $4,238,948 ($549.30/facility × 7,717 facilities) annually. We recognize that many healthcare facilities are also reporting other COVID–19 data to HHS. We believe the benefits of reporting data on the COVID–19 HCP Vaccination reporting measure to monitor, track, and provide transparency for the public on this important tool to combat COVID–19 outweigh the costs of reporting. We welcome comments on the estimated time to collect data and enter it into the NHSN.

We also updated the payment reduction scale using more recent data for the measures in the ESRD QIP measure set. We estimate approximately $215 million in information collection burden, which includes the cost of complying with this rule, and an additional $37 million in estimated payment reductions across all facilities for PY 2025, for an impact of $252 million as a result of the policies we have previously finalized and the policies we have proposed in this proposed rule.

For PY 2026, we estimate that the proposed revisions to the ESRD QIP would result in $215 million in information collection burden, and $37 million in estimated payment reductions across all facilities, for an impact of $252 million as a result of the policies we have previously finalized and the policies we have proposed in this proposed rule.

3. Transfers

We estimate that the proposed updates to the ESRD PPS and AKI payment rate would result in a total in increase of approximately $260 million in payments to ESRD facilities in CY 2023, which includes the amount associated with updates to the outlier thresholds, and updates to the wage index. This estimate includes an increase of approximately $2 million in payments to ESRD facilities in CY 2023 due to the proposed updates to the AKI payment rate, of which approximately 20 percent is increased beneficiary co-insurance payments. We estimate approximately $260 million in transfers from the federal government to ESRD facilities due to increased Medicare program payments and approximately $60 million in transfers from beneficiaries to ESRD facilities due to increased beneficiary co-insurance payments as a result of this proposed rule.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we

[374] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

[375] *https://www.bls.gov/oes/current/oes436013.htm* (accessed on March 29, 2022). The adjusted hourly wage rate of $36.62/hour includes an adjustment of 100 percent of the median hourly wage to account for the cost of overhead, including fringe benefits.

thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $115.22 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* Assuming an average reading speed, we estimate that it would take approximately 214 minutes (3.6 hours) for the staff to review half of this proposed rule, which is approximately 53,500 words. For each entity that reviews the rule, the estimated cost is $414.79 (3.6 hours × $115.22). Therefore, we estimate that the total cost of reviewing this regulation is $118,629.94 ($414.79 × 286).

5. Impact Statement and Table

a. CY 2023 End-Stage Renal Disease Prospective Payment System

(1) Effects on ESRD Facilities

To understand the impact of the changes affecting payments to different categories of ESRD facilities, it is necessary to compare estimated payments in CY 2022 to estimated payments in CY 2023. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of payments in CY 2022 and CY 2023 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this proposed rule, we used CY 2021 data from the Part A and Part B Common Working Files as of February 18, 2022, as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2021 claims to 2022 and 2023 using various updates. The proposed updates to the ESRD PPS base rate are described in section II.B.1.d of this proposed rule. Table 25 shows the impact of the estimated CY 2023 ESRD PPS payments compared to estimated payments to ESRD facilities in CY 2022.

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TABLE 25: Impacts of the Proposed Changes in Payments to ESRD Facilities for CY 2023

Facility Type	Number of Facilities (A)	Number of Treatments (in millions) (B)	Proposed Changes to Outlier Policy (C)	Proposed change to LRS (D)	Proposed Wage Index Changes (E)	Total Percent Change[1] (F)
All Facilities	7,847	35.0	0.7%	0.0%	0.0%	3.1%
Type						
Freestanding	7,471	33.7	0.7%	0.0%	0.0%	3.1%
Hospital based	376	1.4	1.4%	0.0%	-0.1%	3.7%
Ownership Type						
Large dialysis organization	5,964	27.1	0.7%	0.0%	0.0%	3.0%
Regional chain	904	4.3	0.6%	0.2%	0.1%	3.3%
Independent	466	2.1	0.7%	0.3%	-0.1%	3.2%
Hospital based	376	1.4	1.4%	0.0%	-0.1%	3.7%
Unknown	137	0.1	0.5%	0.1%	0.3%	3.3%
Geographic Location						
Rural	1,281	5.0	0.6%	-0.6%	-0.2%	2.3%
Urban	6,566	30.0	0.7%	0.1%	0.0%	3.2%
Census Region						
East North Central	1,222	4.7	0.7%	-0.2%	-0.3%	2.7%
East South Central	618	2.4	0.7%	-0.7%	-0.3%	2.1%

Middle Atlantic	886	4.3	0.8%	0.3%	-0.2%	3.4%
Mountain	436	1.9	0.5%	-0.1%	-0.1%	2.7%
New England	201	1.2	0.6%	0.2%	-0.6%	2.6%
Pacific[2]	966	5.6	0.5%	0.9%	0.6%	4.4%
Puerto Rico and Virgin Islands	52	0.1	0.4%	-1.9%	7.1%	8.1%
South Atlantic	1,827	8.0	0.8%	-0.3%	-0.1%	2.7%
West North Central	514	1.9	0.8%	-0.3%	-0.4%	2.5%
West South Central	1,125	4.8	0.7%	-0.4%	0.2%	2.9%
Facility Size						
Less than 4,000 treatments	1,229	1.9	0.6%	-0.1%	-0.1%	2.8%
4,000 to 9,999 treatments	3,095	10.1	0.7%	-0.2%	-0.1%	2.8%
10,000 or more treatments	3,358	22.9	0.7%	0.1%	0.1%	3.3%
Unknown	165	0.2	0.6%	0.1%	0.3%	3.4%
Percentage of Pediatric Patients						
Less than 2%	7,735	34.8	0.7%	0.0%	0.0%	3.1%
Between 2% and 19%	44	0.2	0.7%	-0.2%	0.1%	2.9%
Between 20% and 49%	12	0.0	0.1%	-0.3%	-0.6%	1.6%
More than 50%	56	0.0	0.2%	0.0%	-0.3%	2.3%

[1] This column includes the impact of the proposed updates in columns (C) through (E) in Table 23, and of the proposed ESRD market basket increase factor for CY 2023 (2.8 percent), reduced by 0.4 percentage point for the productivity adjustment as required by section 1881(b)(14)(F)(i)(II) of the Act. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

[2] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

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Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the proposed changes to the outlier payment policy described in section II.B.1.c of this proposed rule is shown in column C. For CY 2023, the impact on all ESRD facilities as a result of the proposed changes to the outlier payment policy would be a 0.7 percent increase in estimated payments. All ESRD facilities are anticipated to experience a positive effect in their estimated CY 2023 payments as a result of the proposed outlier policy changes.

Column D shows the effect of the proposed update to the LRS for CY 2023 of 55.2 percent. This proposed update is implemented in a budget neutral manner, so the total impact of this proposed change is 0.0 percent; however, there are distributional effects of the change among different categories of ESRD facilities. Facilities located in rural areas are estimated to experience a 0.6 percent decrease in payments, and those located in urban areas are estimated to experience a 0.1 percent increase in payments.

Column E shows the effect of the proposed updates to the wage index, as described in section II.B.1.b of this proposed rule. That is, this column reflects the update from the CY 2022 ESRD PPS wage index continuing to use the 2018 OMB delineations as finalized in the CY 2021 ESRD PPS final rule, with a basis of the FY 2023 pre-floor, pre-reclassified IPPS hospital wage index data in a budget neutral manner. This column also includes the proposed increase of the wage index floor to 0.6000 and the proposed permanent 5-percent cap on wage index decreases. The total impact of this change is 0.0 percent; however, there are distributional effects of the change among different categories of ESRD facilities. The largest estimated increase would be 7.1 percent for facilities located in Puerto Rico and the Virgin Islands, and the largest estimated decrease would be 0.6 percent for facilities in New England.

Column F reflects the overall impact, that is, the effects of the proposed outlier policy changes, the updated wage index, and the proposed payment rate update as described in section II.B.1.d of this proposed rule. The proposed ESRD PPS payment rate update is 2.4 percent, which reflects the proposed ESRDB market basket percentage increase factor for CY 2023 of 2.8 percent and the proposed productivity adjustment of 0.4 percent. We expect that overall ESRD facilities would experience a 3.1 percent increase in estimated payments in CY 2023. The categories of types of facilities in the impact table show impacts ranging from a 1.6 percent increase to an 8.1 percent

increase in their CY 2023 estimated payments.

(2) Effects on Other Providers

Under the ESRD PPS, Medicare pays ESRD facilities a single bundled payment for renal dialysis services, which may have been separately paid to other providers (for example, laboratories, durable medical equipment suppliers, and pharmacies) by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2023, we estimate that the ESRD PPS will have zero impact on these other providers.

(3) Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2023 would be approximately $8.2 billion. This estimate considers a projected decrease in fee-for-service Medicare ESRD beneficiary enrollment of 2.0 percent in CY 2023.

(4) Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount. As a result of the projected 3.1 percent overall increase in the CY 2023 ESRD PPS payment amounts, we estimate that there would be an increase in beneficiary co-insurance payments of 3.1 percent in CY 2023, which translates to approximately $60 million.

(5) Alternatives Considered

(i) CY 2023 Impacts: 2019–2020 Versus 2021 Claims Data

Each year CMS uses the latest available ESRD claims to update the outlier threshold, budget neutrality factor, and payment rates. Due to the COVID–19 PHE, we compared the impact of using CY 2019 or CY 2020 claims against CY 2021 claims to determine if there was any substantial difference in the results that would justify potentially deviating from our longstanding policy to use the latest available data. Analysis suggested that ESRD utilization did not change substantially during the pandemic, likely due to the patients' vulnerability and need for these services. Consequently, we are proposing to use the CY 2021 data because it does not negatively impact ESRD facilities and keeps with our longstanding policy to make updates using the latest available ESRD claims data.

(ii) Proposed Outlier Methodology Alternatives

As discussed in section II.B.1.c.(4) of this proposed rule, we are proposing a change to the methodology used to determine the outlier FDL amounts for adult beneficiaries. We also considered but did not propose maintaining the current outlier methodology or decreasing the 1.0 percent outlier target. In addition, we considered but did not propose a reconciliation process for the outlier methodology.

b. Payment for Renal Dialysis Services Furnished to Individuals With AKI

(1) Effects on ESRD Facilities

To understand the impact of the changes affecting payments to different categories of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is necessary to compare estimated payments in CY 2022 to estimated payments in CY 2023. To estimate the impact among various types of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is imperative that the estimates of payments in CY 2022 and CY 2023 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this proposed rule, we used CY 2021 data from the Part A and Part B Common Working Files as of February 18, 2022, as a basis for Medicare for renal dialysis services furnished to individuals with AKI. We updated the 2021 claims to 2022 and 2023 using various updates. The updates to the AKI payment amount are described in section III.B of this proposed rule. Table 26 shows the impact of the estimated CY 2023 payments for renal dialysis services furnished to individuals with AKI compared to estimated payments for renal dialysis services furnished to individuals with AKI in CY 2022.

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TABLE 26: Impacts of the Proposed Changes in Payments for Renal Dialysis Services Furnished to Individuals with AKI for CY 2023

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Proposed change to LRS (C)	Proposed Wage Index Changes (D)	Total Percent Change[1] (E)
All Facilities	5,308	300.9	0.0%	0.0%	2.4%
Type					
Freestanding	5,188	295.6	0.0%	0.0%	2.4%
Hospital based	120	5.3	-0.3%	0.0%	2.1%
Ownership Type					
Large dialysis organization	4,355	249.8	0.0%	0.0%	2.3%
Regional chain	584	31.6	0.1%	0.0%	2.4%
Independent	198	11.7	0.2%	-0.3%	2.4%
Hospital based[2]	120	5.3	-0.3%	0.0%	2.1%
Unknown	51	2.6	0.1%	0.1%	2.6%
Geographic Location					
Rural	904	49.0	-0.6%	-0.2%	1.6%
Urban	4,404	251.9	0.1%	0.0%	2.5%
Census Region					
East North Central	882	53.1	-0.2%	-0.3%	1.8%
East South Central	414	22.5	-0.7%	-0.4%	1.3%
Middle Atlantic	551	32.3	0.2%	-0.1%	2.6%
Mountain	304	18.4	0.0%	0.1%	2.5%
New England	137	7.3	0.2%	-0.6%	2.0%
Pacific[3]	673	46.1	0.8%	0.6%	3.9%
Puerto Rico and Virgin Islands	1	0.0	-1.9%	7.6%	8.0%
South Atlantic	1,290	71.9	-0.3%	-0.2%	1.9%
West North Central	340	15.1	-0.3%	-0.3%	1.8%
West South Central	716	34.3	-0.4%	0.1%	2.1%
Facility Size					
Less than 4,000 treatments	611	24.9	-0.1%	-0.1%	2.2%
4,000 to 9,999 treatments	2,124	108.7	-0.2%	-0.2%	2.0%
10,000 or more treatments	2,514	163.8	0.1%	0.1%	2.6%
Unknown	59	3.5	0.1%	-0.1%	2.4%
Percentage of Pediatric Patients					
Less than 2%	5,308	300.9	0.0%	0.0%	2.4%
Between 2% and 19%	0	0.0	0.0%	0.0%	0.0%
Between 20% and 49%	0	0.0	0.0%	0.0%	0.0%
More than 50%	0	0.0	0.0%	0.0%	0.0%

[1] This column includes the impact of the updates in columns (C) through (E) in Table 24, and of the proposed ESRD market basket increase factor for CY 2023 (2.8 percent), reduced by 0.4 percentage point for the productivity adjustment as required by section 1881(b)(14)(F)(i)(II) of the Act. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.
[2] Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.
[3] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

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Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of AKI dialysis treatments (in thousands). Column C shows the effect of the proposed update to the LRS for CY 2023 of 55.2 percent. Column D shows the effect of the proposed CY 2023 wage indices, including the proposed increase to the wage index floor and the proposed 5-percent cap on wage index decreases.

Column E shows the overall impact, that is, the effects of the proposed LRS, proposed wage index updates, and the proposed payment rate update of 2.4 percent, which reflects the proposed ESRDB market basket percentage increase factor for CY 2023 of 2.8 percent and the proposed productivity adjustment of 0.4 percent. We expect that overall ESRD facilities would experience a 2.4 percent increase in estimated payments in CY 2023. The categories of types of facilities in the impact table show impacts ranging from an increase of 0.0 percent to 8.0 percent in their CY 2023 estimated payments.

(2) Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we are proposing to update the payment rate for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. The only two Medicare providers and suppliers authorized to provide these outpatient renal dialysis services are hospital outpatient departments and ESRD facilities. The patient and his or her physician make the decision about where the renal dialysis services are furnished. Therefore, this proposed change would have zero impact on other Medicare providers.

(3) Effects on the Medicare Program

We estimate approximately $80 million would be paid to ESRD facilities in CY 2023 as a result of patients with AKI receiving renal dialysis services in the ESRD facility at the lower ESRD PPS base rate versus receiving those services only in the hospital outpatient setting and paid under the outpatient prospective payment system, where services were required to be administered prior to the TPEA.

(4) Effects on Medicare Beneficiaries

Currently, beneficiaries have a 20 percent co-insurance obligation when they receive AKI dialysis in the hospital outpatient setting. When these services are furnished in an ESRD facility, the patients will continue to be responsible for a 20 percent coinsurance. Because the AKI dialysis payment rate paid to ESRD facilities is lower than the outpatient hospital PPS's payment amount, we expect beneficiaries to pay less co-insurance when AKI dialysis is furnished by ESRD facilities.

(5) Alternatives Considered

As we discussed in the CY 2017 ESRD PPS proposed rule (81 FR 42870), we considered adjusting the AKI payment rate by including the ESRD PPS case-mix adjustments, and other adjustments at section 1881(b)(14)(D) of the Act, as well as not paying separately for AKI specific drugs and laboratory tests. We ultimately determined that treatment for AKI is substantially different from treatment for ESRD and the case-mix adjustments applied to ESRD patients may not be applicable to AKI patients and as such, including those policies and adjustment is inappropriate. We continue to monitor utilization and trends of items and services furnished to individuals with AKI for purposes of refining the payment rate in the future. This monitoring will assist us in developing knowledgeable, data-driven proposals.

c. ESRD QIP

(1) Effects of the PY 2023 and PY 2024 ESRD QIP on ESRD Facilities

The ESRD QIP is intended to prevent reductions in the quality of ESRD facility services provided to beneficiaries. The general methodology that we use to determine a facility's TPS is described in our regulations at 42 CFR 413.178(e).

Any reductions in the ESRD PPS payments as a result of a facility's performance under the PY 2023 and PY 2024 ESRD QIP will apply to the ESRD PPS payments made to the facility for services furnished in CY 2023 and CY 2024, respectively, as codified in our regulations at 42 CFR 413.177.

Any reductions in the ESRD PPS payments as a result of a facility's performance under the PY 2025 ESRD QIP will apply to the ESRD PPS payments made to the facility for services furnished in CY 2025, as codified in our regulations at 42 CFR 413.177.

For the PY 2023 ESRD QIP, we estimate that, of the 7,768 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 11.27 percent or 875 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2023. We are presenting an estimate for the PY 2023 ESRD QIP to update the estimated impact that was provided in the CY 2021 ESRD PPS final rule (85 FR 71479 through 71481). If our proposals are finalized as proposed, the total estimated payment reductions for all the 875 facilities expected to receive a payment reduction in PY 2023 would be approximately $9,853,321.90. Facilities that do not receive a TPS do not receive a payment reduction.

Table 27 shows the overall estimated distribution of payment reductions resulting from the PY 2023 ESRD QIP.

TABLE 27: Estimated Distribution of PY 2023 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	6,622	85.25%
0.5%	267	3.44%
1.0%	208	2.68%
1.5%	222	2.86%
2.0%	178	2.29%

*271 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction for PY 2023, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there were available data from EQRS and Medicare claims, excluding the measures that we are proposing to suppress for PY 2023 as discussed in section IV.B.2 of this proposed rule. Payment reduction estimates are calculated using the most recent data available (specified in Table 28) in accordance with the policies finalized in this final rule. Measures used for the simulation are shown in Table 28.

TABLE 28: Data Used to Estimate PY 2023 ESRD QIP Payment Reductions

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey*	N/A	N/A
SRR*	N/A	N/A
SHR*	N/A	N/A
PPPW*	N/A	N/A
Kt/V Dialysis Adequacy Comprehensive*	N/A	N/A
VAT		
Standardized Fistula Ratio	Jan 2018-Dec 2018	Jan 2019-Dec 2019
% Catheter*	N/A	N/A
STrR	Jan 2018-Dec 2018	Jan 2019-Dec 2019

*Note: We are proposing to suppress the ICH CAHPS measure, the SRR clinical measure, the SHR clinical measure, the PPPW clinical measure, the Kt/V Dialysis Adequacy Comprehensive measure, and the Long-Term Catheter Rate measure for PY 2023, as discussed in section IV.B.2 of this proposed rule.

For all measures except the six measures we are proposing to suppress in IV.B.2 of this proposed rule, as well as the STrR measure, measures with less than 11 patients for a facility were not included in that facility's TPS. For the STrR reporting measure, facilities were required to have at least 10 patient-years at risk in order to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table that were consistent with the proposed polices outlined in sections IV.B and IV.C of this proposed rule. Facility reporting measure scores were estimated using available data from CY 2019 and CY 2020 for MedRec. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2023 for each facility resulting from this proposed rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2019 and December 2019 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

(2) Effects of the PY 2025 ESRD QIP on ESRD Facilities

For the PY 2025 ESRD QIP, we estimate that, of the 7,717 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 41 percent or 3,171 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2025. We are presenting an estimate for the PY 2025 ESRD QIP to update the estimated impact that was provided in the CY 2022 ESRD PPS final rule (86 FR 62008 through 62011). If our proposals are finalized as proposed, the total estimated payment reductions for all the 3,171 facilities expected to receive a

payment reduction in PY 2025 would be approximately $37,167,805.51. Facilities that do not receive a TPS do not receive a payment reduction.

Table 29 shows the overall estimated distribution of payment reductions resulting from the PY 2025 ESRD QIP.

TABLE 29: Estimated Distribution of PY 2025 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	4,214	57.06%
0.5%	1,769	23.95%
1.0%	999	13.53%
1.5%	332	4.50%
2.0%	71	0.96%

*332 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction for PY 2025, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there were available data from EQRS and Medicare claims. Payment reduction estimates are calculated using the most recent data available (specified in Table 28) in accordance with the policies proposed in this proposed rule. Measures used for the simulation are shown in Table 30.

TABLE 30: Data Used to Estimate PY 2025 ESRD QIP Payment Reductions

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SRR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SHR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
PPPW*	N/A	Jan 2019-Dec 2019
Kt/V Dialysis Adequacy Comprehensive	Jan 2018-Dec 2018	Jan 2019-Dec 2019
VAT		
Standardized Fistula Ratio	Jan 2018-Dec 2018	Jan 2019-Dec 2019
% Catheter	Jan 2018-Dec 2018	Jan 2019-Dec 2019
STrR	Jan 2018-Dec 2018	Jan 2019-Dec 2019

*Note: PPPW score is based on achievement score only.

For all measures except the SHR clinical measure, the SRR clinical measure, and the STrR measure, measures with less than 11 patients for a facility were not included in that facility's TPS. For the SHR clinical measure and the SRR clinical measure, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, in order to be included in the facility's TPS. For the STrR reporting measure, which we are proposing to convert to a clinical measure beginning in PY 2025 in section IV.E.1.b of this proposed rule, facilities were required to have at least 10 patient-years at risk in order to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table that were consistent with the proposed polices outlined in section IV.E of this proposed rule. Facility reporting measure scores were estimated using available data from CY 2019 and CY 2020 for MedRec. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2025 for each facility resulting from this proposed rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2019 and December 2019 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 31 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2025. The table also details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and

facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period we are using for the PY 2025 ESRD QIP, the actual impact of the PY 2025 ESRD QIP may vary significantly from the values provided here.

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TABLE 31: Estimated Impact of QIP Payment Reductions to ESRD Facilities for PY 2025

	Number of Facilities	Number of Treatments 2019 (in millions)	Number of Facilities with QIP Score	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction (percent change in total ESRD payments)
All Facilities	7,717	43.4	7,385	3,171	-0.34%
Facility Type:					
Freestanding	7,339	41.7	7,039	3,007	-0.33%
Hospital-based	378	1.7	346	164	-0.43%
Ownership Type:					
Large Dialysis	5,886	33.6	5,718	2,304	-0.30%
Regional Chain	887	5.3	852	407	-0.41%
Independent	515	2.8	467	296	-0.62%
Hospital-based (non-chain)	378	1.7	346	164	-0.43%
Unknown	51	0.0	2	0	-0.00%
Facility Size:					
Large Entities	6,773	38.9	6,570	2,711	-0.31%
Small Entities[1]	893	4.5	813	460	-0.54%
Unknown	51	0.0	2	0	-0.00%
Rural Status:					
1) Yes	1,268	6.3	1,242	421	-0.26%
2) No	6,449	37.1	6,143	2,750	-0.35%
Census Region:					
Northeast	1,060	6.4	1,001	426	-0.33%
Midwest	1,716	7.9	1,666	751	-0.36%
South	3,506	20.1	3,368	1,623	-0.38%
West	1,374	8.5	1,291	327	-0.17%
US Territories[2]	61	0.4	59	44	-0.68%
Census Division:					
Unknown	9	0.1	8	4	-0.43%
East North Central	1,213	5.6	1,172	583	-0.41%
East South Central	609	3.2	593	272	-0.35%
Middle Atlantic	859	5.1	808	366	-0.35%
Mountain	428	2.3	405	96	-0.17%
New England	201	1.3	193	60	-0.23%
Pacific	946	6.2	886	231	-0.17%
South Atlantic	1,794	10.4	1,707	821	-0.39%
West North Central	503	2.3	494	168	-0.23%
West South Central	1,103	6.5	1,068	530	-0.40%
US Territories[2]	52	0.3	51	40	-0.72%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,248	2.4	1,096	338	-0.26%
4,000-9,999 treatments	2,905	11.9	2,904	1,147	-0.31%
Over 10,000 treatments	3,384	28.9	3,383	1,684	-0.38%
Unknown	180	0.2	2	2	-0.75%

[1]Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status.

[2]Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

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(3) Effects of the PY 2026 ESRD QIP on ESRD Facilities

For the PY 2026 ESRD QIP, we estimate that, of the 7,717 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 41 percent or 3,171 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2026. The total payment reductions for all the 3,171 facilities expected to receive a payment reduction is approximately $37,167,805.51. Facilities that do not receive a TPS do not receive a payment reduction.

Table 32 shows the overall estimated distribution of payment reductions resulting from the PY 2026 ESRD QIP.

TABLE 32: Estimated Distribution of PY 2026 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	4,214	57.06%
0.5%	1,769	23.95%
1.0%	999	13.53%
1.5%	332	4.50%
2.0%	71	0.96%

*Note: 332 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction in PY 2026, we scored each facility on achievement and improvement on several clinical measures we have previously finalized and for which there were available data from EQRS and Medicare claims. Payment reduction estimates were calculated using the most recent data available (specified in Table 32) in accordance with the policies proposed in this proposed rule. Measures used for the simulation are shown in Table 33.

TABLE 33: Data Used to Estimate PY 2026 ESRD QIP Payment Reductions

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance Period
ICH CAHPS Survey	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SRR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
SHR	Jan 2018-Dec 2018	Jan 2019-Dec 2019
PPPW*	N/A	Jan 2019-Dec 2019
Kt/V Dialysis Adequacy Comprehensive	Jan 2018-Dec 2018	Jan 2019-Dec 2019
VAT		
Standardized Fistula Ratio	Jan 2018-Dec 2018	Jan 2019-Dec 2019
% Catheter	Jan 2018-Dec 2018	Jan 2019-Dec 2019
STrR	Jan 2018-Dec 2018	Jan 2019-Dec 2019

*Note: PPPW score is based on achievement score only

For all measures except the SHR clinical measure, the SRR clinical measure, and the STrR measure, measures with less than 11 patients for a facility were not included in that facility's TPS. For SHR and SRR, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, in order to be included in the facility's TPS. For the STrR reporting measure, which we are proposing to convert to a clinical measure beginning in PY 2025 in section IV.E.1.b of this proposed rule, facilities were required to have at least 10 patient-years at risk in order to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table that incorporates the policies outlined in section IV.F of this proposed rule. Facility reporting measure scores were estimated using available data from CY 2019 and CY 2020 for MedRec. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2026 for each facility resulting from this proposed rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2019 and December 2019 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 34 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2026. The table details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period we are using for the PY 2026 ESRD QIP, the actual impact of the PY 2026 ESRD QIP may vary significantly from the values provided here.

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TABLE 34: Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2026

	Number of Facilities	Number of Treatments 2019 (in millions)	Number of Facilities with QIP Score	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction (percent change in total ESRD payments)
All Facilities	7,717	43.4	7,385	3,171	-0.34%
Facility Type:					
Freestanding	7,339	41.7	7,039	3,007	-0.33%
Hospital-based	378	1.7	346	164	-0.43%
Ownership Type:					
Large Dialysis	5,886	33.6	5,718	2,304	-0.30%
Regional Chain	887	5.3	852	407	-0.41%
Independent	515	2.8	467	296	-0.62%
Hospital-based (non-chain)	378	1.7	346	164	-0.43%
Unknown	51	0.0	2	0	-0.00%
Facility Size:					
Large Entities	6,773	38.9	6,570	2,711	-0.31%
Small Entities[1]	893	4.5	813	460	-0.54%
Unknown	51	0.0	2	0	-0.00%
Rural Status:					
1) Yes	1,268	6.3	1,242	421	-0.26%
2) No	6,449	37.1	6,143	2,750	-0.35%
Census Region:					
Northeast	1,060	6.4	1,001	426	-0.33%
Midwest	1,716	7.9	1,666	751	-0.36%
South	3,506	20.1	3,368	1,623	-0.38%
West	1,374	8.5	1,291	327	-0.17%
US Territories[2]	61	0.4	59	44	-0.68%
Census Division:					
Unknown	9	0.1	8	4	-0.43%
East North Central	1,213	5.6	1,172	583	-0.41%
East South Central	609	3.2	593	272	-0.35%
Middle Atlantic	859	5.1	808	366	-0.35%
Mountain	428	2.3	405	96	-0.17%
New England	201	1.3	193	60	-0.23%
Pacific	946	6.2	886	231	-0.17%
South Atlantic	1,794	10.4	1,707	821	-0.39%
West North Central	503	2.3	494	168	-0.23%
West South Central	1,103	6.5	1,068	530	-0.40%
US Territories[2]	52	0.3	51	40	-0.72%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,248	2.4	1,096	338	-0.26%
4,000-9,999 treatments	2,905	11.9	2,904	1,147	-0.31%
Over 10,000 treatments	3,384	28.9	3,383	1,684	-0.38%
Unknown	180	0.2	2	2	-0.75%

[1]Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status.

[2]Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

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(4) Effects on Other Providers

The ESRD QIP is applicable to ESRD facilities. We are aware that several of our measures impact other providers. For example, with the introduction of the SRR clinical measure in PY 2017 and the SHR clinical measure in PY 2020, we anticipate that hospitals may experience financial savings as facilities work to reduce the number of unplanned readmissions and hospitalizations. We are exploring various methods to assess the impact these measures have on hospitals and other facilities, such as through the impacts of the Hospital Readmissions Reduction Program and the Hospital-Acquired Condition Reduction Program, and we intend to continue examining the interactions between our quality programs to the greatest extent feasible.

(5) Effects on the Medicare Program

For PY 2026, we estimate that the ESRD QIP would contribute approximately $37,167,805.51 in Medicare savings. For comparison, Table 35 shows the payment reductions that we estimate will be applied by the ESRD QIP from PY 2018 through PY 2026.

TABLE 35: Estimated ESRD QIP Aggregate Payment Reductions for Payment Years 2018 through 2026

Payment Year	Estimated Payment Reductions
PY 2026	$37,167,805.51
PY 2025	$37,167,805.51
PY 2024	$17,104,030.59 (86 FR 62011)
PY 2023	$9,853,321.90
PY 2022	$0[376] (86 FR 62011)
PY 2021	$32,196,724 (83 FR 57062)
PY 2020	$31,581,441 (81 FR 77960)
PY 2019	$15,470,309 (80 FR 69074)
PY 2018	$11,576,214 (79 FR 66257)

(6) Effects on Medicare Beneficiaries

The ESRD QIP is applicable to ESRD facilities. Since the Program's inception, there is evidence on improved performance on ESRD QIP measures. As we stated in the CY 2018 ESRD PPS final rule, one objective measure we can examine to demonstrate the improved quality of care over time is the improvement of performance standards (82 FR 50795). As the ESRD QIP has refined its measure set and as facilities have gained experience with the measures included in the Program, performance standards have generally continued to rise. We view this as evidence that facility performance (and therefore the quality of care provided to Medicare beneficiaries) is objectively improving. We are in the process of monitoring and evaluating trends in the quality and cost of care for patients under the ESRD QIP, incorporating both existing measures and new measures as they are implemented in the Program. We would provide additional information about the impact of the ESRD QIP on beneficiaries as we learn more. However, in future years we are interested in examining these impacts through the analysis of available data from our existing measures.

(7) Alternatives Considered

In section IV.B.2 of this proposed rule, we are proposing to suppress six measures for PY 2023 due to the impacts of the COVID–19 PHE on CY 2021 data. We considered not suppressing these six measures for PY 2023. However, we concluded that measure suppression was appropriate under our previously finalized measure suppression policy due to the impact of the COVID–19 PHE on these PY 2023 ESRD QIP measures. This approach would help to ensure that a facility would not be penalized for performance on measures which have been impacted by extraordinary circumstances beyond the facility's control.

d. ETC Model

(1) Overview

The ETC Model is a mandatory payment model designed to test payment adjustments to certain dialysis and dialysis-related payments, as discussed in the Specialty Care Models final rule (85 FR 61114) and the CY 2022 ESRD PPS final rule (86 FR 61874), for ESRD facilities and for Managing Clinicians for claims with dates of service from January 1, 2021 to June 30, 2027. The requirements for the ETC Model are set forth in 42 CFR part 512, subpart C.

The changes proposed in this proposed rule (discussed in detail in section V.B of this proposed rule) would impact model payment adjustments for PPA Period 5, starting July 1, 2024. The proposed change that is most likely to affect the impact estimate for the ETC Model is the proposal to add a parameter to the PPA achievement scoring methodology such that an ETC Participant's aggregation group must have a positive home dialysis rate or transplant rate to receive an achievement score for that rate, as described in section V.B.1 of this proposed rule. We do not anticipate that the proposal to clarify the requirements for qualified staff to furnish and bill kidney disease patient education services under the ETC Model's Medicare program waivers, described in section V.B.2 of this proposed rule, would affect the impact estimate for the ETC Model.

The ETC Model is not a total cost of care model. ETC Participants will still bill FFS Medicare, and items and services not subject to the ETC Model's payment adjustments will continue to be paid as they would in the absence of the ETC Model.

(2) Data and Methods

A stochastic simulation was created to estimate the financial impacts of the proposed changes to the ETC Model relative to baseline expenditures, where baseline expenditures were defined as data from CYs 2018 and 2019 without the proposed changes applied. The simulation relied upon statistical assumptions derived from retrospectively constructed ESRD facilities' and Managing Clinicians' Medicare dialysis claims, transplant claims, and transplant waitlist data reported during 2018 and 2019, the most recent years of complete data available before the start of the ETC Model. Both datasets and the risk-adjustment methodologies for the ETC Model were developed by the CMS Office of the Actuary (OACT).

For the modeling exercise used to estimate changes in payment to providers and suppliers and the resulting savings to Medicare, OACT maintained the previous method to simulate identification of ETC Participants (including aggregation group construction), beneficiary attribution (and exclusions), calculation

[376] In the CY 2022 ESRD PPS final rule, we finalized our proposed special scoring methodology and payment policy for PY 2022 (86 FR 61918 through 61919). Under this policy, we will not apply any payment reductions to ESRD facilities for PY 2022.

of home dialysis rates and transplant rates, calculation of achievement benchmarks, and calculation of improvement scores. For a detailed description of this methodology, see the detailed economic analysis included in the CY 2022 ESRD PPS final rule (86 FR 62012 through 62014).

Beginning for MY5 and beyond, the PPA achievement scoring methodology included one modification. Specifically, achievement scores were only awarded for the home dialysis rate or the transplant rate to ETC Participants in aggregation groups with a home dialysis rate or transplant rate greater than zero, respectively, in accordance with the proposed change described in section V.B.1 of this proposed rule. To clarify, no changes to the achievement scoring methodology were made to MY1 through MY4. For a detailed description of the methodology for simulating achievement scoring methodology, see the CY 2022 ESRD PPS final rule (86 FR 60213 through 60214).

No changes were made to the payment structure for the HDPA calculation, as no changes were proposed. Similarly, no changes were made to the kidney disease patient education services utilization and cost calculations, as the proposed change does not impact expected utilization. For a detailed description of this methodology, see the detailed economic analysis included in the CY 2022 ESRD PPS final rule (86 FR 62014).

(3) Medicare Estimate—Primary Specification, Assume Proposed Achievement Scoring Update

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TABLE 36: Estimates of Medicare Program Savings (Rounded $M) for ESRD Treatment Choices (ETC) Model

	Year of Model							
	2021	2022	2023	2024	2025	2026	2027	6.5 Year Total*
Net Impact to Medicare Spending	15	9	-1	-9	-12	-19	-9	-28
Overall PPA Net & HDPA	14	7	-3	-11	-15	-22	-12	-43
Clinician PPA Downward Adjustment		-1	-2	-2	-3	-3	-2	-13
Clinician PPA Upward Adjustment		0	1	1	1	1	1	6
Clinician PPA Net		0	-1	-1	-2	-2	-1	-7
Clinician HDPA	0	0	0					0
Facility Downward Adjustment		-9	-20	-25	-31	-39	-21	-145
Facility Upward Adjustment		5	12	15	18	19	10	79
Facility PPA Net		-3	-8	-10	-14	-20	-11	-66
Facility HDPA	14	10	6					29
Total PPA Downward Adjustment		-9	-22	-27	-34	-43	-23	-158
Total PPA Upward Adjustment		6	13	16	19	21	11	84
Total PPA Net		-4	-9	-11	-15	-22	-12	-73
Total HDPA	14	10	6					30
Kidney Disease Patient Education Services Costs	0	1	1	1	1	1	1	5
HD Training Costs	1	1	1	1	2	2	2	10

*Totals may not sum due to rounding and from beneficiaries that have dialysis treatment spanning multiple years. Negative spending reflects a reduction in Medicare spending. The kidney disease patient education services benefit costs are less than $1M each year, but are rounded up to $1M to show what years they apply to. Similarly, the HD Training Costs are less than $1M for years 2021-2024, but are rounded up to $1M to indicate that costs were applied those years.

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Table 36 summarizes the estimated impact of the ETC Model when the achievement benchmarks for each year are set using the average of the home dialysis rates for year *t*-1 and year *t*-2 for the HRRs randomly selected for participation in the ETC Model. We estimate that the Medicare program will save a net total of $43 million from the PPA and HDPA between January 1, 2021 and June 30, 2027 less $15 million in increased training and education expenditures. Therefore, the net impact to Medicare spending is estimated to be $28 million in savings. This is consistent with the net impact to Medicare spending estimated for the CY 2022 ESRD PPS final rule, in which the net impact to Medicare spending was

also estimated to be $28 million in savings (86 FR 62014 through 62016).

In Table 36, negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase. The results for this table were generated from an average of 400 simulations under the assumption that benchmarks are rolled forward with a 1.5-year lag. For a detailed description of the key assumptions underlying the impact estimate, see the CY 2022 ESRD PPS final rule (86 FR 60214 through 60216).

As was the case in the Specialty Care Models final rule (85 FR 61353) and the CY 2022 ESRD PPS final rule (86 FR 61874), the projections do not include the Part B premium revenue offset because the payment adjustments under the ETC Model will not affect beneficiary cost-sharing. Any potential effects on Medicare Advantage capitation payments were also excluded from the projections. This approach is consistent with how CMS has previously conveyed the primary FFS effects anticipated for an uncertain model without also assessing the potential impact on Medicare Advantage rates.

(4) Effects on the Home Dialysis Rate, the Transplant Rate, and Kidney Transplantation

The changes proposed in this proposed rule would not impact the findings reported for the effects of the ETC Model on the home dialysis rate or the transplant rate described in the CY 2022 ESRD PPS final rule (86 FR 62017).

(5) Effects on Kidney Disease Patient Education Services and HD Training Add-Ons

The changes proposed in this proposed rule would not impact the findings reported for the effects of the ETC Model on kidney disease patient education services and HD training add-ons described in the Specialty Care Models final rule (85 FR 61355) or the CY 2022 ESRD PPS final rule (85 FR 62017).

(6) Effects on Medicare Beneficiaries

The changes proposed in this proposed rule would not impact the findings reported for the effects of ETC Model on Medicare beneficiaries regarding the ETC Model's likelihood of incentivizing ESRD facilities and Managing Clinicians to improve access to home dialysis and transplantation for Medicare beneficiaries.

As previously noted in the Specialty Care Models final rule (85 FR 61357) and the CY 2022 ESRD PPS final rule (86 FR 62017), we continue to anticipate that the ETC Model will have a negligible impact on the cost to beneficiaries receiving dialysis. Under current policy, Medicare FFS beneficiaries are generally responsible for 20 percent of the allowed charge for services furnished by providers and suppliers. This policy will remain the same for most beneficiaries under the ETC Model. However, we will waive certain requirements of title XVIII of the Act as necessary to test the PPA and HDPA under the ETC Model and hold beneficiaries harmless from any effect of these payment adjustments on cost sharing.

In addition, the Medicare beneficiary's quality of life has the potential to improve if the beneficiary elects to have home dialysis, or nocturnal in-center dialysis, as opposed to in-center dialysis. As discussed in the Specialty Care Models final rule, studies have found that home dialysis patients experienced improved quality of life as a result of their ability to continue regular work schedules or life plans; as well as better overall, physical, and psychological health in comparison to other dialysis options (85 FR 61264 through 61270).

(7) Alternatives Considered

Throughout this proposed rule, we have identified our policies and alternatives that we have considered, and provided information as to the likely effects of these alternatives and rationale for each of our policies

This proposed rule addresses a model specific to ESRD. It provides descriptions of the requirements that we would waive, identifies the performance metrics and payment adjustments proposed to be tested, and presents rationales for our proposals, and where relevant, alternatives considered. We carefully considered the alternatives to this proposed rule. For context related to alternatives previously considered when establishing and modifying the ETC Model we refer readers to the Specialty Care Models final rule (85 FR 61114) and the CY 2022 ESRD PPS final rule (86 FR 61874), respectively, for more information on policy-related stakeholder comments, our responses to those comments, and statements of final policy preceding the limited modifications proposed here.

E. Accounting Statement

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), we have prepared an accounting statement in Table 37 showing the classification of the impact associated with the provisions of this proposed rule.

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TABLE 37: Accounting Statement: Classification of Estimated Transfers and Costs/Savings	
ESRD PPS and AKI (CY 2023)	
Category	**Transfers**
Annualized Monetized Transfers	$260 million
From Whom to Whom	Federal government to ESRD providers
Category	**Transfers**
Increased Beneficiary Co-insurance Payments	$60 million
From Whom to Whom	Beneficiaries to ESRD providers
ESRD QIP for PY 2023	
Category	Transfers
Annualized Monetized Transfers	-$9 million
From Whom to Whom	Federal government to ESRD providers.
ESRD QIP for PY 2025	
Category	Transfers
Annualized Monetized Transfers	-$37 million
From Whom to Whom	Federal government to ESRD providers.
ESRD QIP for PY 2026	
Category	Transfers
Annualized Monetized Transfers	-$37 million
From Whom to Whom	Federal government to ESRD providers
ETC Model for July 1, 2022 through June 30, 2027	
Category	**Transfers**
Annualized Monetized Transfers	$0.03 million
From Whom to Whom	Federal government to ESRD facilities and Managing Clinicians

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F. Regulatory Flexibility Act Analysis (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis. Individuals and states are not included in the definition of a small entity. Therefore, the number of small entities estimated in this RFA analysis includes the number of ESRD facilities that are either considered small businesses or nonprofit organizations.

According to the Small Business Administration's (SBA) size standards [377], an ESRD facility is classified as a small business if it has total revenues of less than $41.5 million in any 1 year. For the purposes of this analysis, we exclude the ESRD facilities that are owned and operated by LDOs and regional chains, which would have total revenues of more than $9.3 billion in any year when the total revenues for all locations are combined for each business (LDO or regional chain), and are not, therefore, considered small businesses. Because we lack data on individual ESRD facilities' receipts, we cannot determine the number of small proprietary ESRD facilities or the proportion of ESRD facilities' revenue derived from Medicare payments. Therefore, we assume that all ESRD facilities that are not owned by LDOs or regional chains are considered small businesses. Accordingly, we consider the 466 facilities that are independent and 376 facilities that are hospital-based, as shown in the ownership category in Table 25, to be small businesses. These facilities represent approximately 11 percent of all ESRD facilities in our data set.

Additionally, we identified in our analytic file that there are 817 facilities that are considered nonprofit organizations, which is approximately 10 percent of all ESRD facilities in our data set. In total, accounting for the 376 nonprofit ESRD facilities that are also considered small businesses, there are 1,283 ESRD facilities that are either small businesses or nonprofit organizations, which is approximately 16 percent of all ESRD facilities in our data set.

For the ESRD PPS updates proposed in this rule, a hospital-based ESRD facility (as defined by type of ownership, not by type of ESRD facility) is estimated to receive a 3.7 percent increase in payments for CY 2023. An independent facility (as defined by ownership type) is estimated to receive a 3.2 percent increase in payments for CY 2023. As shown in Table 25, we estimate that the overall revenue impact of this proposed rule on all ESRD facilities is a positive increase to Medicare payments by approximately 3.1 percent.

For AKI dialysis, we are unable to estimate whether patients would go to ESRD facilities, however, we have estimated there is a potential for $80 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities.

For the ESRD QIP, we estimate that of the 3,171 ESRD facilities expected to receive a payment reduction as a result

[377] More information available at *http://www.sba.gov/content/small-business-size-standards* (Kidney Dialysis Centers are listed as North American Industry Classification System (NAICS) code 621492 with a size standard of $41.5 million).

of their performance on the PY 2025 ESRD QIP, 460 are ESRD small entity facilities. We present these findings in Table 29 (''Estimated Distribution of PY 2025 ESRD QIP Payment Reductions'') and Table 31 (''Estimated Impact of QIP Payment Reductions to ESRD Facilities for PY 2025'').

For the ETC Model, this proposed rule includes as ETC Participants Managing Clinicians and ESRD facilities required to participate in the Model, pursuant to § 512.325(a). We assume for the purposes of the regulatory impact analysis that the great majority of Managing Clinicians are small entities by meeting the SBA definition of a small business. The greater majority of ESRD facilities are not small entities, as they are owned, partially or entirely, by entities that do not meet the SBA definition of small entities. Under the ETC Model, the HDPA is a positive adjustment on payments for specified home dialysis and home dialysis-related services. The PPA, which includes both positive and negative adjustments on payments for dialysis and dialysis-related services, excludes aggregation groups with fewer than 132 attributed beneficiary-months during the relevant year. The aggregation methodology groups ESRD facilities owned in whole or in part by the same dialysis organization within a Selected Geographic Area and Managing Clinicians billing under the same Tax Identification Number (TIN) within a Selected Geographic Area. Taken together, the low volume threshold exclusions and aggregation policies, coupled with the fact that the ETC Model affects Medicare payment only for select services furnished to Medicare FFS beneficiaires; we have determined that the provisions of the proposed rule for the ETC Model would not have a significant impact on spending for a substantial number of small entities.

The HDPA is a positive adjustment on payments for specified home dialysis and home dialysis-related services. The PPA, which includes both positive and negative adjustments on payments for dialysis and dialysis-related services, excludes aggregation groups with fewer than 132 attributed beneficiary-months during the relevant year. The aggregation methodology groups ESRD facilities owned in whole or in part by the same dialysis organization within a Selected Geographic Area and Managing Clinicians billing under the same Tax Identification Number (TIN) within a Selected Geographic Area, which increases the statistical liability of the home dialysis rate and the transplant rate for ETC Participants in the aggregation group. Taken together, the low volume threshold exclusions and aggregation policies, coupled with the fact that the ETC Model affects Medicare payment only for select services furnished to Medicare FFS beneficiaires; we have determined that the provisions of the proposed rule would not have a significant impact on spending for a substantial number of small entities.

The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically ''significant'' only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. As a result, since the overall estimated impact of these proposed updates is a net increase of greater than 3 percent in revenue across almost all categories of ESRD facility, the Secretary has determined that this proposed rule will have a significant positive revenue impact on a substantial number of ESRD facilities identified as small entities.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this proposed rule will have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 121 rural hospital-based ESRD facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 121 rural hospital-based ESRD facilities will experience an estimated 2.8 percent increase in payments. Therefore, the Secretary has certified that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

G. Unfunded Mandates Reform Act Analysis (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold is approximately $165 million. This proposed rule does not mandate any requirements for state, local, or tribal governments, in the aggregate, or by the private sector of more than $165 million in any 1 year. Moreover, HHS interprets UMRA as applying only to unfunded mandates. We do not interpret Medicare payment rules as being unfunded mandates, but simply as conditions for the receipt of payments from the federal government for providing services that meet federal standards. This interpretation applies whether the facilities or providers are private, state, local, or tribal.

H. 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. We have reviewed this proposed rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of states, local or Tribal governments.

VIII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IX. Files Available to the Public via the Internet

The Addenda for the annual ESRD PPS proposed and final rule will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the internet and will be posted on the CMS website under the regulation number, CMS–1768–P at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.* In addition to the Addenda, limited data set files are available for purchase at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/EndStageRenalDiseaseSystemFile.* Readers who experience any problems accessing the Addenda or LDS files, should contact CMS by sending an email to CMS at the following mailbox: *ESRDPayment@cms.hhs.gov.*

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on June 13, 2022.

List of Subjects

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 512

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 1. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 2. Section 413.178 is amended by revising paragraphs (a)(8) and (d)(2) and adding paragraph (i) to read as follows:

§ 413.178 ESRD quality incentive program.

(a) * * *

(8) *Minimum total performance score (mTPS)* means, with respect to a payment year except payment year 2023, the total performance score that an ESRD facility would receive if, during the baseline period, it performed at the 50th percentile of national ESRD facility performance on all clinical measures and the median of national ESRD facility performance on all reporting measures.

* * * * *

(d) * * *

(2) For purposes of paragraph (d)(1) of this section, the baseline period that applies to each of payment year 2023 and payment year 2024 is calendar year 2019 for purposes of calculating the achievement threshold, benchmark and minimum total performance score, and calendar year 2019 for purposes of calculating the improvement threshold. The baseline period that applies to payment year 2025 is calendar year 2021 for purposes of calculating the achievement threshold, benchmark and minimum total performance score, and calendar year 2022 for purposes of calculating the improvement threshold, and the performance period that applies to payment year 2025 is calendar year 2023. Beginning with payment year 2026, the performance period and corresponding baseline periods are each advanced 1 year for each successive payment year.

* * * * *

(i) *Special Rules for Payment Year 2023.* (1) CMS will calculate a measure rate for, but will not score facility performance on or include in the TPS for any facility under paragraph (e) of this section, the following measures: Standardized Hospitalization Ratio (SHR) clinical measure, Standardized Readmission Ratio (SRR) clinical measure, Long-Term Catheter Rate clinical measure, ICH CAHPS clinical measure, Percentage of Prevalent Patients Waitlisted (PPPW) clinical measure, and Kt/V Dialysis Adequacy clinical measure.

(2) The mTPS for payment year 2023 is the total performance score that an ESRD facility would receive if, during the calendar year 2019 baseline period, it performed at the 50th percentile of national ESRD facility performance on Standardized Fistula Rate clinical measure, Hypercalcemia clinical measure, NHSN Blood Stream Infection (BSI) clinical measure, and the median of national ESRD facility performance on Clinical Depression Screening and Follow-Up reporting measure, Standardized Transfusion Ratio (STrR) reporting measure, Ultrafiltration Rate reporting measure, NHSN Dialysis Event reporting measure, and Medication Reconciliation (MedRec) reporting measure.

■ 3. Section 413.231 is amended by adding paragraphs (c) and (d) to read as follows:

§ 413.231 Adjustment for wages.

* * * * *

(c) Beginning January 1, 2023, CMS applies a cap on decreases to the wage index, such that the wage index applied to an ESRD facility is not less than 95 percent of the wage index applied to that ESRD facility in the prior calendar year.

(d) Beginning January 1, 2023, CMS applies a floor of 0.6000 to the wage index, such that the wage index applied to an ESRD facility is not less than 0.6000.

§ 413.234 [Amended]

■ 4. In § 413.234, amend paragraph (a) by adding the word ''functional'' before the word ''equivalent'' in the definition of ''Oral-only drug''.

PART 512—RADIATION ONCOLOGY MODEL AND END STAGE RENAL DISEASE TREATMENT CHOICES MODEL

■ 5. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

■ 6. Section 512.370 is amended by revising paragraph (b) introductory text and adding paragraph (b)(3) to read as follows:

§ 512.370 Benchmarking and scoring.

* * * * *

(b) *Achievement Scoring.* CMS assesses ETC Participant performance at the aggregation group level on the home dialysis rate and transplant rate against achievement benchmarks constructed based on the home dialysis rate and transplant rate among aggregation groups of ESRD facilities and Managing Clinicians located in Comparison Geographic Areas during the Benchmark Year. Achievement benchmarks are calculated as described in paragraph (b)(1) of this section and, for MY3 through MY10, are stratified as described in paragraph (b)(2) of this section. For MY5 through MY10, the ETC Participant's achievement score is subject to the restriction described in paragraph (b)(3) of this section.

* * * * *

(3) For MY5 through MY10, CMS will assign an achievement score to an ETC Participant for the home dialysis rate or the transplant rate only if the ETC Participant's aggregation group has a home dialysis rate or a transplant rate greater than zero for the MY.

* * * * *

■ 7. Section 512.397 is amended by revising paragraph (b)(1) to read as follows:

§ 512.397 ETC Model Medicare program waivers and additional flexibilities.

* * * * *

(b) * * *

(1) CMS waives the requirement under section 1861(ggg)(2)(A)(i) of the Act and § 410.48(a) of this chapter that only doctors, physician assistants, nurse practitioners, and clinical nurse specialists can furnish kidney disease patient education services to allow kidney disease patient education services to be provided by clinical staff (as defined at § 512.310) under the direction of and incident to the services of the Managing Clinician who is an ETC Participant. The kidney disease patient education services may be

furnished only by qualified staff (as defined at § 512.310). Beginning MY5, only clinical staff that are not leased from or otherwise provided by an ESRD facility or related entity may furnish kidney disease patient education services pursuant to the waiver described in this section.

* * * * *

Dated: June 17, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2022–13449 Filed 6–21–22; 4:15 pm]

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Part III

Federal Communications Commission

47 CFR Part 1
Assessment and Collection of Regulatory Fees for Fiscal Year 2022; Proposed Rule

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[MD Docket Nos. 21–190; MD Docket Nos. 22–223; FCC 22–39; FR ID 91674]

Assessment and Collection of Regulatory Fees for Fiscal Year 2022

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) seeks comment on revising the fee schedule of FY 2022 regulatory fees to collect $381,950,000 in regulatory fees by fiscal year end. Regulatory fee collections offset one hundred percent of the Commission's budget.

DATES: Submit comments on or before July 5, 2022; and reply comments on or before July 18, 2022.

ADDRESSES: Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments identified by MD Docket No. 22–223, by any of the following methods below. Comments and reply comments may be filed using the Commission's Electronic Comment Filing System (ECFS). *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998).

1. *Comment Filing Procedures.* Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998).

2. Effective March 19, 2020, and until further notice, the Commission no longer accepts any hand or messenger delivered filings. This is a temporary measure taken to help protect the health and safety of individuals, and to mitigate the transmission of COVID–19. In the event that the Commission announces the lifting of COVID–19 restrictions, a filing window will be opened at the Commission's office located at 9050 Junction Drive, Annapolis, MD 20701.

3. Pursuant to § 1.49 of the Commission's rules, 47 CFR 1.49, parties to this proceeding must file any documents in this proceeding using the Commission's Electronic Comment Filing System (ECFS): *http://apps.fcc.gov/ecfs/.*

4. *Materials in Accessible Formats.* To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at 202–418–0530 (voice).

5. *Availability of Documents.* Comments, reply comments, and *ex parte* submissions will be available via ECFS. Documents will be available electronically in ASCII, Microsoft Word, and/or Adobe Acrobat. When the FCC Headquarters reopens to the public, these documents will also be available for public inspection during regular business hours in the FCC Reference Center, Federal Communications Commission, 45 L Street NE, Washington, DC 20554.

For detailed instructions for submitting comments and additional information on the rulemaking process, *see* the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Roland Helvajian, Office of Managing Director at (202) 418–0444.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Proposed Rulemaking* (NPRM), FCC 22–39, MD Docket No. 21–190, and MD Docket No. 22–223, adopted on June 1, 2022 and released on June 2, 2022. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center, 445 12th Street SW, Room CY–A257, Portals II, Washington, DC 20554, and may also be purchased from the Commission's copy contractor, BCPI, Inc., Portals II, 445 12th Street SW, Room CY–B402, Washington, DC 20554. Customers may contact BCPI, Inc. via their website, *http://www.bcpi.com,* or call 1–800–378–3160. This document is available in alternative formats (computer diskette, large print, audio record, and braille). Persons with disabilities who need documents in these formats may contact the FCC by email: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

I. Procedural Matters

6. *Ex Parte Information.* The proceeding initiated by this *NPRM,* in which we seek comment on proposals as described above, shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's ex parte rules. Persons making ex parte presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral ex parte presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the ex parte presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda, or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during ex parte meetings are deemed to be written ex parte presentations and must be filed consistent with § 1.1206(b) of the Commission's rules. In proceedings governed by § 1.49(f) of the Commission's rules or for which the Commission has made available a method of electronic filing, written ex parte presentations and memoranda summarizing oral ex parte presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's ex parte rules.

7. *Initial Regulatory Flexibility Analysis.* An initial regulatory flexibility analysis (IRFA) is contained in this summary. Comments to the IRFA must be identified as responses to the IRFA and filed by the deadlines for comments on the *NPRM.* The Commission will send a copy of the *NPRM,* including the IRFA, to the Chief Counsel for Advocacy of the Small Business Administration.

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

I. Introduction

9. For fiscal year (FY) 2022, the Commission is required to collect $381,950,000 in regulatory fees for FY 2022, pursuant to sections 9 and 9A of the Communications Act of 1934, as amended (Communications Act), and the Commission's FY 2022 Appropriations Act. In this *NPRM,* we seek comment on associated changes to the non-geostationary orbit (NGSO) space stations regulatory fee rates. We also seek comment on the Commission's proposed regulatory fees for FY 2022 as set forth in Tables 2 and 3 in addition to other issues including: continuing to use our methodology for calculating television broadcaster regulatory fees based on population; calculating the costs of collection of regulatory fees in establishing the annual de minimis threshold; and how our proposals may promote or inhibit advances in diversity, equity, inclusion, and accessibility.

II. Background

10. Congress requires the Commission to assess and collect regulatory fees each year in an amount that can reasonably be expected to equal the amount of its annual salaries and expenses (S&E) appropriation. Regulatory fees cover direct costs, such as salaries and expenses; indirect costs, such as overhead functions; statutorily required tasks that do not directly equate with oversight and regulation of a particular regulatee but instead benefit the Commission and the industry as a whole; and support costs such as rent, utilities, and equipment. Regulatory fees also cover the costs incurred in oversight and regulation of entities that are statutorily exempt from paying regulatory fees (*i.e.,* governmental and nonprofit entities, amateur radio operators, and noncommercial radio and television stations), entities that are exempt from payment of FY 2022 regulatory fees because their total assessed annual regulatory fees fall below the annual de minimis threshold, and entities whose regulatory fees are waived. Pursuant to section 9(d) of the Communications Act, the Commission's methodology for assessing regulatory fees must ''reflect the full-time equivalent number of employees within the bureaus and offices of the Commission, adjusted to take into account factors that are reasonably related to the benefits provided to the payor of the fee by the Commission's activities.'' For FY 2022, the Commission must recover $381,950,000, as set forth in the FY 2022 Consolidated Appropriations Act.

11. Each year, early in the fiscal year, the Commission receives full time equivalent (FTE) data from its Human Resources Office, and identifies FTE data at the core bureau level (*i.e.,* direct FTEs), which is then used to determine the FTE allocations for the four core bureaus. This FTE data is then filtered down to the various fee categories within each core bureau based on the fee category percentages for each bureau. After the number of direct FTEs is determined within each core bureau of the Commission, a percentage of the total amount to be collected in regulatory fees for a given fiscal year is calculated for each core bureau based on the number of direct FTEs within a core bureau. The total of the percentages for each core bureau must equal 100% of the amount to be collected. The total percentage for a core bureau is then used to calculate the percentages for the various regulatory fee categories within each core bureau, as provided by the Commission's bureaus. Thus, the regulatory fee categories within each core bureau make up a percentage of a core bureau's total percentage to be collected in regulatory fees.

12. These percentages, either at the regulatory fee category level within a core bureau or summed up to the core bureau level, represent the dollar amount of regulatory fees to be collected by multiplying each fee category percentage by the target goal to be collected. For example, the Wireline Competition Bureau, a core bureau, has direct FTEs that constitute 33.74% of all regulatory fees to be collected. The Wireline Competition Bureau also has two fee categories from which 33.74% of the fees are to be collected: (1) the Interstate Telecommunications Service Provider Fee (ITSP) fee category constitutes 32.62%, and (2) the Toll Free Number fee category constitutes 1.12% for a total sum of 33.74%. The percentage for each fee category represents the amount to collect in regulatory fees for that fee category—for example, for the ITSP fee category, 32.62% amounts to $124.59 million from an FY 2022 target goal of $381,950,000. This dollar amount ($124.59 million) divided by the estimated units for the ITSP fee category determines the fee rate, which is then rounded to the nearest $5, where applicable. Indirect FTEs are then allocated proportionally based on the allocation percentage of direct FTEs of each core bureaus.

13. The indirect FTEs are the FTEs in the Enforcement Bureau, Consumer and Governmental Affairs Bureau, Public Safety and Homeland Security Bureau, Chairwoman's and Commissioners' offices, Office of the Managing Director, Office of General Counsel, Office of the Inspector General, Office of Communications Business Opportunities, Office of Engineering and Technology, Office of Legislative Affairs, Office of Workplace Diversity, Office of Media Relations, Office of Economics and Analytics, and Office of Administrative Law Judges, along with some FTEs in the Wireline Competition Bureau and the International Bureau that the Commission has previously classified as indirect for regulatory fee purposes. Unlike the work of direct FTEs, the work of FTEs designated as indirect benefits the Commission and the industry as a whole and is not specifically focused on the regulatees and licensees of a core bureau. The high percentage of indirect FTEs is indicative of the fact that many Commission activities and costs are not limited to a particular fee category and instead benefit the Commission and its work as a whole.

14. In section 9 of the Communications Act, Congress prescribed a method of collecting an amount equal to the full S&E appropriation by keying the regulatory fee assessment to FTE burden. As a result, the fee assigned to each regulatory fee category relates to the FTE burden associated with their oversight and regulation by the relevant core bureaus. Because the total amount the Commission must collect in an offsetting collection generally changes each fiscal year, payors' regulatory fees will also typically change each fiscal year as a mathematical consequence of the changes in the total amount to be collected, the number of Commission FTEs, and projected unit estimates for each fee category. Beyond those changed collection requirements, consideration of changes, additions, or deletions to the regulatory fee schedule is focused on the Commission's direct FTE cost burden related to the regulatory fee category at issue within each core bureau.

15. *Adjustments and Amendments to Regulatory Fee Schedule.* Each year, the Commission is required to adjust the schedule of regulatory fees to ''(A) reflect unexpected increases or decreases in the number of units subject to the payment of such fees; and (B) result in the collection of the amount required'' by the Commission's annual appropriation. Each year the Commission issues a Notice of Proposed Rulemaking to seek comment on its methodology for assessing regulatory fees and the proposed regulatory fees for the fiscal year.

III. Notice of Proposed Rulemaking

16. In this annual regulatory fee *NPRM,* we seek comment on our methodology for assessing regulatory fees and on the schedule of FY 2022 regulatory fees as set forth in Tables 2 and 3. We also seek comment on associated changes to the NGSO space station regulatory fee rates in addition to several other issues such as continuing to use our methodology for calculating television broadcaster regulatory fees based on population; calculating the costs of collection of regulatory fees in establishing the annual de minimis threshold; and how our proposals may promote or inhibit advances in diversity, equity, inclusion, and accessibility.

A. Assessment of Regulatory Fees

17. *Methodology for Assessing Regulatory Fees.* Congress has required us to collect $381,950,000 in regulatory fees for FY 2022. In doing so, section 9 of the Communications Act requires us to set regulatory fees to ''reflect the full-time equivalent number of employees within the bureaus and offices of the Commission adjusted to take into account factors that are reasonably related to the benefits provided to the payor of the fee by the Commission's activities.'' We implement this directive by first looking to the core bureaus within the Commission in order to identify the number of direct non-auction FTEs from each core bureau and then categorize the remaining non-auction FTEs and other Commission costs as indirect. Once the direct FTEs are identified, we then allocate fees to specific fee categories within each core bureau. These proportional calculations allocate all Commission non-auction related costs across all fee categories. We find that our methodology is consistent with section 9 of the Communications Act which requires us to base our methodology on the number of FTEs in calculating regulatory fees. We seek comment on this methodology and on the schedule of FY 2022 regulatory fees as set forth in Tables 2 and 3. Any proposals or comments requesting a change or modification to our proposed FY 2022 regulatory fees should include a thorough analysis showing a sufficient basis for making the change and provide alternative options for the Commission to meet its statutory obligation to collect the full amount of the appropriation by the end of the fiscal year. Commenters should also indicate how such alternative options are fair, administrable, and sustainable.

18. *Allocating FTEs.* Consistent with past practices, we propose to base the allocation of fee categories for FY 2022 on the Commission's calculation of FTEs in each regulatory fee category. Each year, early in the fiscal year, the Commission receives FTE data from the Commission's Human Resources Office, and identifies FTE data at the core bureau level (direct FTEs). This FTE data is then filtered down to the various fee categories within each core bureau. The total FTEs for each fee category include the direct FTEs associated with that category plus a proportional allocation of indirect FTEs. Applying the requirements of section 9 of the Communications Act to calculate regulatory fees, we propose to allocate the total collection target across all regulatory fee categories. Each regulatee within a fee category then pays its proportionate share based on an objective measure. To calculate fees for each licensee, we identify ''units'' used to calculate the fees. For example, broadcast licensees' fees will vary by population served and commercial mobile radio service (CMRS) wireless licensees will pay fees based on their number of subscribers. These calculations are illustrated in Table 2. The sources for the unit estimates that are used in these calculations are listed in Table 4.

19. In sum, there are 329 direct FTEs for FY 2022, distributed among the core bureaus as follows International Bureau (28), Wireless Telecommunications Bureau (70), Wireline Competition Bureau (111), and the Media Bureau (120). This results in 8.51% of the FTE allocation for International Bureau regulatees; 21.28% of the FTE allocation for Wireless Telecommunications Bureau regulatees; 33.74% of the FTE allocation for Wireline Competition Bureau regulatees; and 36.47% of FTE allocation for Media Bureau regulatees. There are in turn 943 indirect FTEs spread across the Commission: Enforcement Bureau (187), Consumer and Governmental Affairs Bureau (111), Public Safety and Homeland Security Bureau (98), part of the International Bureau (52), part of the Wireline Competition Bureau (38), Chairman and Commissioners' offices (22), Office of the Managing Director (136), Office of General Counsel (70), Office of the Inspector General (47), Office of Communications Business Opportunities (10), Office of Engineering and Technology (66), Office of Legislative Affairs (8), Office of Workforce Diversity (4), Office of Media Relations (12), Office of Economics and Analytics (78), and Office of Administrative Law Judges (4). Allocating these indirect FTEs based on the direct FTE allocations yields an additional 80.26 FTEs attributable to International Bureau regulatees, 200.64 FTEs attributable to Wireless Telecommunications Bureau regulatees, 318.16 FTEs attributable to Wireline Competition Bureau regulatees, and 343.95 FTEs attributable to Media Bureau regulatees.

20. Based on these allocations and the requirement to collect $381,950,000 in regulatory fees this year, we project collecting approximately $32.51 million (8.51%) in fees from International Bureau regulatees; $81.27 million (21.28%) in fees from Wireless Telecommunications Bureau regulatees; $128.86 million (33.74%) from Wireline Competition Bureau regulatees; and $139.31 million (36.47%) from Media Bureau regulatees. We set specific regulatory fees in Table 3 so that regulatees within a fee category pay their proportionate share based on an objective measure (*e.g.,* revenues or number of subscribers). The proposed fees are based on the established methodology, applied to the allocated direct FTEs and based on the Commission's appropriation amount of $381,950,000. We seek comment on our methodology. Commenters proposing adjustments to our methodology should explain the basis for their proposals.

1. Regulatory Fee Rates for Space Stations

21. We seek comment on the proposed regulatory fees for space stations as provided in Table 2. In 2021, the Commission adopted new NGSO space stations regulatory fee subcategories: ''less complex'' and ''other,'' both under the broader category of ''Space Stations (Non-Geostationary Orbit).'' In the *FY 2021 Report and Order,* 86 FR 52742 (Sept. 22, 2021), the Commission subsequently adopted the proposal from the *FY 2021 NPRM,* 86 FR 52429 (Sept. 21, 2021), to allocate 20% of NGSO space station regulatory fees to ''less complex'' NGSO space stations and 80% of NGSO regulatory fees to ''other'' NGSO space stations. As discussed above, in this proceeding, we determine a fee methodology for small satellites, and integrate the small satellite fee category into the NGSO space stations fee category. Accordingly, in Table 2, we have included the proposed fees for NGSO space stations calculated by assessing the fees that small satellites will pay in FY 2022, reducing that amount from the overall NGSO space stations fee category, and allocating the remaining NGSO space station fees 20/

80 using the two new fee subcategories: ''less complex'' NGSO space stations and all other NGSO space stations identified as ''other'' NGSO space stations.''

22. Below is a table illustrating the proposed NGSO fee rates for FY 2022. These proposed regulatory fees are also listed in Tables 2 and 3. We seek comment on these proposed regulatory fees. Commenters proposing alternative should explain the basis for their proposals.

Proposed NGSO—small satellite fee (per license)	Proposed NGSO—other space station fee (per system)	Proposed NGSO—less complex space station fee (per system)
$12,145	$338,020	$140,840

23. *Spacecraft Performing On-Orbit Servicing and Rendezvous and Proximity Operations.* Two commenters propose the creation of additional fee categories, citing similarities between the characteristics of small satellites and those other satellite services commenters contend should have a separate fee. Spaceflight proposes that the Commission create a separate fee category for spacecraft performing on-orbit services (OOS), which would include deployment, rendezvous and proximity services. Spaceflight posits that OOS spacecraft share characteristics of small satellites and ''less complex'' NGSO systems thereby justifying the creation of a new and lower fee category. Spaceflight also distinguishes between OOS spacecraft and traditional NGSO satellites in that OOS spacecraft have limited duration and scope of use as well as a limited number of earth stations; require a smaller investment in OOS technology; require less ongoing regulation owing to the shorter duration of OOS spacecraft; will likely be licensed on a shared use basis. Spaceflight also notes that OOS spacecraft are licensed on a non-interference basis without the need for processing round procedures or post-processing round disputes over matters such as interference protection and spectrum priority. In addition, Astroscale proposes that the Commission create a new fee category for rendezvous and proximity operations (RPO). Astroscale submits that a Commission proceeding to create service rules and a corresponding fee category for RPO services would provide much needed permanency and clarity to support this nascent infrastructure. In allocating this fee, Astroscale argues that the Commission should consider the similarities that RPO services share with small satellites, such as one-way data communication, and with ''less complex'' NGSO systems, such as the less-intensive use of ground stations.

24. At this time, we tentatively conclude that it would be premature to adopt new fee categories for OOS and RPO operations. To date, there have been a limited number of such operations and these have been treated on a case-by-case basis. Except for GSO servicing missions, we expect that most OOS and RPO operations will be NGSO, but we tentatively conclude that it is too early to identify exactly where operations such as those in low-Earth orbit (LEO) might fit into the regulatory fee structure in the future. Thus, at this time, we do not have a record sufficient to propose to establish a fee category(ies) and appropriate methodology for assessing such a fee category(ies). We propose that, until we gain more experience in regulating such systems, we continue to regulate these systems as we have and consider OOS and RPO spacecraft licensing on a mission-by-mission basis. We seek comment on these tentative conclusions. Commenters that nonetheless favor a new fee category or categories should fully explain the basis for their positions, including how the Commission might identify exactly where these operations might fit into the regulatory fee structure.

25. However, although we do not adopt a new regulatory and corresponding fee category for OOS and RPO spacecraft at this time, we further seek comment on whether and how to assess fees for these types of spacecraft, and other types of satellites servicing other satellites, which operate near to the GSO arc. Specifically, we seek comment on whether a satellite servicing other satellites that operates above the GSO arc should be treated as a GSO space station for regulatory fee purposes. We also seek comment on what factors should be considered in determining whether the servicing spacecraft should be assessed regulatory fees separately. For example, what percentage of time are the satellites co-located with a GSO satellite?

B. Full-Service Television Broadcaster Fees

26. In the *FY 2020 Report and Order,* 85 FR 59864 (Sept. 23, 2020), we completed the transition to a population-based full-service broadcast television regulatory fee. We do not reopen that decision relating to these regulatory fees being based on population at this time. For FY 2022, we propose to continue to assess fees for full-power broadcast television stations based on the population covered by a full-service broadcast television station's contour and seek comment on our mechanism, described below, for how we will calculate the regulatory fee based on the previously decided population-based methodology. As described in Table 7, we propose adopting a factor of .88 of one cent ($.008803) per person served for FY 2022 full-service broadcast television station fees. The population data for broadcasters' service areas are extracted from the TVStudy database, based on a station's projected noise-limited service contour. The population data for each licensee and the population-based fee (population multiplied by $.008803 for each full-service broadcast television station), including each satellite station is listed in Table 7. We seek comment on these proposed fees. Any commenters suggesting different ways to measure population-based fees for full-service television broadcasters should indicate the proposed fees and the underlying calculation and basis for the fees.

C. De Minimis Threshold

27. We seek comment on how to calculate the costs of collection of regulatory fees in establishing the annual de minimis threshold of $1,000. Section 9(e)(2) of the Communications Act permits the Commission to exempt a party from paying regulatory fees if ''in the judgment of the Commission, the cost of collecting a regulatory fee established under this section from a party would exceed the amount collected from such party. . . .'' NAB proposes that we increase the de minimis threshold, above $1,000, in order to assist small broadcasters. We remind commenters that the text of section 9(e)(2) of the Communications Act does not include language

suggesting that such considerations be used in determining the cost of collecting a regulatory fee for purposes of setting the de minimis threshold.

28. In the *FY 2019 Report and Order,* 84 FR 50890 (Sept. 26, 2019), the Commission concluded that section 9(e)(2) of the Communications Act codifies our authority to adopt a de minimis exemption. At that time, the Commission analyzed the average cost of collecting delinquent debt and estimated that the Commission's cost of collecting the debt would exceed $1,000. The Commission determined that its administrative debt collection process involves many steps, including data compilation, preparation and validation; invoicing; debt transfer for third party collection; responding to debtor questions and disputes; and processing payments. Accordingly, the Commission retained the de minimis threshold for annual regulatory fee payors at $1,000.

29. We seek comment on NAB's proposal to increase the de minimis threshold. Commenters should discuss how we should calculate the costs of collection of regulatory fees and whether the cost of collecting a regulatory fee begins after the regulatory fees are due and once delinquencies occur. Alternatively, should the cost of collection begin when the Commission collects data on a payor's regulatory fee status, generally prior to the regulatory fee due date? Commenters advocating a higher annual de minimis threshold should discuss which steps in the debt collection process should be included in ''the cost of collecting a regulatory fee.'' For example, should the Commission also consider the costs associated with reviewing and resolving waiver requests and installment payment requests? Commenters suggesting an increase should indicate what the threshold should be increased to and the factual and statutory basis for such an increase. Commenters should also explain if the proposed definition of costs of collection is consistent with other uses of the term in the U.S. Code with respect to collection of federal fees.

D. Indirect Full Time Equivalents

30. As discussed above, the Commission has previously reclassified certain direct FTEs as indirect for regulatory purposes due to the nature of their work assignments. We seek comment on whether such reclassifications, on balance, produce a more accurate regulatory fee assessment. If reclassification is appropriate in certain circumstances, should we consider different calculation methods when reclassified FTEs work on issues that clearly do not benefit certain classes of licensees? If so, how should we adjust our calculation method? In addition, how frequently should the Commission revisit such reclassifications to ensure that the FTEs accurately reflect the work of the relevant Bureau? Are the current reclassifications still appropriate? To what extent does reclassification undermine the Commission's rationale for retaining its current direct/indirect methodology?

E. New Regulatory Fee Categories

31. In the *FY 2021 NPRM,* we sought comment on ''whether we should adopt new regulatory fee categories and on ways to improve our regulatory fee process regarding any and all categories of service.'' We invite additional comment in order to help inform our consideration of these issues.

F. Digital Equity and Inclusion

32. Finally, the Commission, as part of its continuing effort to advance digital equity for all, including people of color, persons with disabilities, persons who live in rural or tribal areas, and others who are or have been historically underserved, marginalized, or adversely affected by persistent poverty or inequality, invites comment on any equity-related considerations and benefits (if any) that may be associated with the proposals and issues discussed herein. Specifically, we seek comment on how our proposals may promote or inhibit advances in diversity, equity, inclusion, and accessibility, as well the scope of the Commission's relevant legal authority. We note that diversity and equity considerations, however, do not allow the Commission to shift fees from one party of fee payors to another nor to raise fees for any purpose other than as an offsetting collection in the amount of our annual S&E appropriation.

IV. Procedural Matters

33. Included below are procedural items as well as our current payment and collection methods. We include these payments and collection procedures here as a useful way of reminding regulatory fee payers and the public about these aspects of the annual regulatory fee collection process.

34. *Credit Card Transaction Levels.* In accordance with *Treasury Financial Manual,* Volume I, Part 5, Chapter 7000, Section 7045—*Limitations on Card Collection Transactions,* the highest amount that can be charged on a credit card for transactions with federal agencies is $24,999.99. Transactions greater than $24,999.99 will be rejected. This limit applies to single payments or bundled payments of more than one bill. Multiple transactions to a single agency in one day may be aggregated and treated as a single transaction subject to the $24,999.99 limit. Customers who wish to pay an amount greater than $24,999.99 should consider available electronic alternatives such as Visa or MasterCard debit cards, Automates Clearing House (ACH) debits from a bank account, and wire transfers. Each of these payment options is available after filing regulatory fee information in Fee Filer. Further details will be provided regarding payment methods and procedures at the time of FY 2022 regulatory fee collection in Fact Sheets, *https://www.fcc.gov/regfees.*

35. *Payment Methods.* During the fee season for collecting regulatory fees, regulatees can pay their fees by credit card through *Pay.gov*, ACH, debit card, or by wire transfer. Additional payment instructions are posted on the Commission's website at *https://transition.fcc.gov/fees/regfees.html.* The receiving bank for all wire payments is the U.S. Treasury, New York, NY (TREAS NYC). Any other form of payment (*e.g.,* checks, cashier's checks, or money orders) will be rejected. For payments by wire, an FCC Form 159–E should still be transmitted via fax so that the Commission can associate the wire payment with the correct regulatory fee information. The fax should be sent to the Commission at (202) 418–2843 at least one hour before initiating the wire transfer (but on the same business day) so as not to delay crediting their account. Regulatees should discuss arrangements (including bank closing schedules) with their bankers several days before they plan to make the wire transfer to allow sufficient time for the transfer to be initiated and completed before the deadline. Complete instructions for making wire payments are posted at *https://transition.fcc.gov/fees/wiretran.html.*

36. *Standard Fee Calculations and Payment Dates.* The Commission will accept fee payments made in advance of the window for the payment of regulatory fees. The responsibility for payment of fees by service category is as follows:

- *Media Services:* Regulatory fees must be paid for initial construction permits that were granted on or before October 1, 2021 for AM/FM radio stations, VHF/UHF broadcast television stations, and satellite television stations. Regulatory fees must be paid for all broadcast facility licenses granted on or before October 1, 2021.
- *Wireline (Common Carrier) Services:* Regulatory fees must be paid

for authorizations that were granted on or before October 1, 2021. In instances where a permit or license is transferred or assigned after October 1, 2021, responsibility for payment rests with the holder of the permit or license as of the fee due date. Audio bridging service providers are included in this category. For Responsible Organizations (RespOrgs) that manage Toll Free Numbers (TFN), regulatory fees should be paid on all working, assigned, and reserved toll free numbers as well as toll free numbers in any other status as defined in § 52.103 of the Commission's rules. The unit count should be based on toll free numbers managed by RespOrgs on or about December 31, 2021.

- *Wireless Services:* Commercial Mobile Radio Service (CMRS) cellular, mobile, and messaging services (fees based on number of subscribers or telephone number count): Regulatory fees must be paid for authorizations that were granted on or before October 1, 2021. The number of subscribers, units, or telephone numbers on December 31, 2021 will be used as the basis from which to calculate the fee payment. In instances where a permit or license is transferred or assigned after October 1, 2021, responsibility for payment rests with the holder of the permit or license as of the fee due date.
- *Wireless Services, Multi-year fees:* The first seven regulatory fee categories in our Schedule of Regulatory Fees pay ''small multi-year wireless regulatory fees.'' Entities pay these regulatory fees in advance for the entire amount period covered by the five-year or ten-year terms of their initial licenses, and pay regulatory fees again only when the license is renewed, or a new license is obtained. We include these fee categories in our rulemaking to publicize our estimates of the number of ''small multi-year wireless'' licenses that will be renewed or newly obtained in FY 2022.
- *Multichannel Video Programming Distributor (MVPD) Services (cable television operators, Cable Television Relay Service (CARS) licensees, direct broadcast satellite (DBS), and internet Protocol TV (IPTV)):* Regulatory fees must be paid for the number of basic cable television subscribers as of December 31, 2021. Regulatory fees also must be paid for CARS licenses that were granted on or before October 1, 2021. In instances where a permit or license is transferred or assigned after October 1, 2021, responsibility for payment rests with the holder of the permit or license as of the fee due date. For providers of DBS service and IPTV-based MVPDs, regulatory fees should be paid based on a subscriber count on or about December 31, 2021. In instances where a permit or license is transferred or assigned after October 1, 2021, responsibility for payment rests with the holder of the permit or license as of the fee due date.
- *International Services:* Regulatory fees must be paid for earth stations that were licensed (or authorized) on or before October 1, 2021. Regulatory fees must also be paid for Geostationary orbit space stations (GSO) and non-geostationary orbit satellite systems (NGSO), and the two NGSO subcategories ''Other'' and ''Less Complex,'' that were licensed and operational on or before October 1, 2021. Licensees of small satellites that were licensed and operational on or before October 1, 2021 must also pay regulatory fees. In instances where a permit or license is transferred or assigned after October 1, 2021, responsibility for payment rests with the holder of the permit or license as of the fee due date.
- *International Services* (*Submarine Cable Systems, Terrestrial and Satellite Services*): Regulatory fees for submarine cable systems are to be paid on a per cable landing license basis based on lit circuit capacity as of December 31, 2021. Regulatory fees for terrestrial and satellite IBCs are to be paid based on active (used or leased) international bearer circuits as of December 31, 2021, in any terrestrial or satellite transmission facility for the provision of service to an end user or resale carrier. When calculating the number of such active circuits, entities must include circuits used by themselves or their affiliates. For these purposes, ''active circuits'' include backup and redundant circuits as of December 31, 2021. Whether circuits are used specifically for voice or data is not relevant for purposes of determining that they are active circuits. In instances where a permit or license is transferred or assigned after October 1, 2021, responsibility for payment rests with the holder of the permit or license as of the fee due date.

37. *CMRS and Mobile Services Assessments.* The Commission will compile data from the Numbering Resource Utilization Forecast (NRUF) report that is based on ''assigned'' telephone number (subscriber) counts that have been adjusted for porting to net Type 0 ports (''in'' and ''out''). We have included non-geographic numbers in the calculation of the number of subscribers for each CMRS provider in Table 2 and the CMRS regulatory fee factor proposed in Table 3. CMRS provider regulatory fees will be calculated and should be paid based on the inclusion of non-geographic numbers. CMRS providers can adjust the total number of subscribers, if needed. This information of telephone numbers (subscriber count) will be posted on the Commission's electronic filing and payment system (Fee Filer) along with the carrier's Operating Company Numbers (OCNs).

38. A carrier wishing to revise its telephone number (subscriber) count can do so by accessing Fee Filer and follow the prompts to revise their telephone number counts. Any revisions to the telephone number counts should be accompanied by an explanation or supporting documentation. The Commission will then review the revised count and supporting documentation and either approve or disapprove the submission in Fee Filer. If the submission is disapproved, the Commission will contact the provider to afford the provider an opportunity to discuss its revised subscriber count and/or provide additional supporting documentation. If we receive no response from the provider, or we do not reverse our initial disapproval of the provider's revised count submission, the fee payment must be based on the number of subscribers listed initially in Fee Filer. Once the timeframe for revision has passed, the telephone number counts are final and are the basis upon which CMRS regulatory fees are to be paid. Providers can view their final telephone counts online in Fee Filer. A final CMRS assessment letter will not be mailed out.

39. Because some carriers do not file the NRUF report, they may not see their telephone number counts in Fee Filer. In these instances, the carriers should compute their fee payment using the standard methodology that is currently in place for CMRS Wireless services (*i.e.,* compute their telephone number counts as of December 31, 2021), and submit their fee payment accordingly. Whether a carrier reviews its telephone number counts in Fee Filer or not, the Commission reserves the right to audit the number of telephone numbers for which regulatory fees are paid. In the event that the Commission determines that the number of telephone numbers that are paid is inaccurate, the Commission will bill the carrier for the difference between what was paid and what should have been paid.

V. List of Tables

TABLE 1

Commenter	Abbreviated commenter name	Date filed
Comments to the FY 2021 Report and Order and NPRM MD Docket No. 21–190		
ACT—The App Association, American Lighting Association (ALA), American Public Gas Association (APGA), Association of Equipment Manufacturers (AEM), Association of Home Appliance Manufacturers (AHAM), Bluetooth SIG, Consumer Technology Association (CTA), Information Technology industry Council (ITI), National Electrical Manufacturers Association (NEMA), North American Association of Food Equipment Manufacturers (NAFEM), Outdoor Power Equipment Institute (OPEI), Plumbing Manufacturers International (PMI), Power Tool Institute (PTI), Telecommunications Industry Association (TIA), and Wi-SUN Alliance.	ACT Joint Commenters	10/21/21
Alliance of Automotive Innovation	Auto Innovators	10/21/21
Association of Home Appliance Manufacturers	AHAM	10/21/21
Astro Digital US, Inc	Astro Digital	10/21/21
Astroscale US	Astroscale	10/21/21
Computer and Communications Industry Association, Digital Media Association, INCOMPAS, and Internet Association.	CCIA Joint Commenters	10/21/21
Consumer Technology Association	CTA	10/21/21
DECT Forum	DECT Forum	10/21/21
Engine	Engine	10/21/21
Eutelsat Communications SA	Eutelsat	10/21/21
Hearing Industries Association	HIA	10/21/21
Information Technology Industry Council	ITI	10/21/21
Intuitive Machines, LLC	Intuitive Machines	10/21/21
Low Power Radio Association	LPRA	10/22/21
Motor and Equipment Manufacturers Association	MEMA	10/21/21
National Association of Broadcasters	NAB	10/21/21
National Electrical Manufacturers Association	NEMA	10/21/21
NCTA—The Internet & Television Association	NCTA	10/21/21
New America's Open Technology Institute, Public Knowledge, the Benton Institute for Broadband & Society, Access Humboldt, Center for Rural Strategies, Tribal Digital Village, the Institute for Local Self Reliance, and the Schools, Health, Libraries & Broadband Coalition.	Public Interest Spectrum Commenters	10/21/21
Dr. Scott Palo	Palo	10/21/21
RBC Signals, LLC	RBC Signals	10/21/21
Spaceflight, Inc	Spaceflight	10/21/21
TechFreedom	TechFreedom	10/21/21
Telesat Canada, Kepler Communications Inc., WorldVu Satellites Limited (d/b/a OneWeb), O3b Limited, and SES Americom, Inc.	Satellite Coalition	10/21/21
US Telecom—The Broadband Association	USTelecom ex parte	10/21/21
Wi-Fi Alliance®	Wi-Fi Alliance	10/21/21
Wireless Internet Service Providers Association	WISPA	10/21/21
Reply Comments to FY 2021 Report and Order and NPRM MD Docket No. 21–190		
ABC Television Affiliates Association, CBS Television Network Affiliates Association, FBC Television Affiliates Association, and NBC Television Affiliates.	Television Affiliates Associations	11/5/21
Alabama Broadcasters Association, Alaska Broadcasters Association, Arizona Broadcasters Association, Arkansas Broadcasters Association, California Broadcasters Association, Colorado Broadcasters Association, Connecticut Broadcasters Association, Florida Association of Broadcasters, Georgia Association of Broadcasters, Hawaii Association of Broadcasters, Idaho State Broadcasters Association, Illinois Broadcasters Association, Indiana Broadcasters Association, Iowa Broadcasters Association, Kansas Association of Broadcasters, Kentucky Broadcasters Association, Louisiana Association of Broadcasters, Maine Association of Broadcasters, MD/DC/DE Broadcasters Association, Massachusetts Broadcasters Association, Michigan Association of Broadcasters, Minnesota Broadcasters Association, Mississippi Association of Broadcasters, Missouri Broadcasters Association, Montana Broadcasters Association, Nebraska Broadcasters Association, Nevada Broadcasters Association, New Hampshire Association of Broadcasters, New Jersey Broadcasters Association, New Mexico Broadcasters Association, The New York State Broadcasters Association, Inc., North Carolina Association of Broadcasters, North Dakota Broadcasters Association, Ohio Association of Broadcasters, Oklahoma Association of Broadcasters, Oregon Association of Broadcasters, Pennsylvania Association of Broadcasters, Radio Broadcasters Association of Puerto Rico, Rhode Island Broadcasters Association, South Carolina Broadcasters Association, South Dakota Broadcasters Association, Tennessee Association of Broadcasters, Texas Association of Broadcasters, Utah Broadcasters Association, Vermont Association of Broadcasters, Virginia Association of Broadcasters, Washington State Association of Broadcasters, West Virginia Broadcasters Association, Wisconsin Broadcasters Association, and Wyoming Association of Broadcasters.	State Broadcasters Associations	11/5/21
Consumer Technology Association	CTA	11/5/21
CTIA—The Wireless Association®	CTIA	11/5/21
Entertainment Software Association	ESA	11/5/21
Itron, Inc	Itron	11/5/21
John Jaworski	Jaworski	11/5/21
Mobile & Wireless Forum	MWF	11/5/21
National Association of Broadcasters	NAB	11/5/21
NCTA—The Internet & Television Association	NCTA	11/5/21
R Street Institute	R Street	11/4/21
Dr. Scott Palo	Palo	11/5/21
Telesat Canada, Kepler Communications Inc., WorldVu Satellites Limited (d/b/a OneWeb), O3b Limited, and SES Americom, Inc.	Satellite Coalition	11/5/21

TABLE 1—Continued

Commenter	Abbreviated commenter name	Date filed
Utilities Technology Council	UTC	11/5/21
Wi-Fi Alliance®	Wi-Fi Alliance	11/5/21
Wireless Internet Service Providers Association	WISPA	11/5/21
Ex Parte Comments to FY 2021 Report and Order and NPRM MD Docket No. 21–190		
NCTA—The Internet & Television Association	NCTA	11/15/21
Thomas Lawler	Lawler	11/16/21
ACT—The App Association, American Lighting Association (ALA), Association of Equipment Manufacturers (AEM), Association of Home Appliance Manufacturers (AHAM), Bluetooth SIG, Consumer Technology Association (CTA), Information Technology industry Council (ITI), National Electrical Manufacturers Association (NEMA), Telecommunications Industry Association (TIA), and Wi-SUN Alliance.	NEMA	11/3/21
Kepler, SES, Telesat	Kepler, SES, Telesat	3/10/22
National Association of Broadcasters	NAB	3/3/22
National Association of Broadcasters	NAB	3/31/22
National Rural Electric Cooperative Association	NRECA	12/27/21
Open Technology Institute at New America (OTI) and Public Knowledge (PK)	OTI, PK	12/6/21
Wireless Internet Service Providers Association	WISPA	12/3/21

Regulatory fees for the categories shaded in gray are collected by the Commission in advance to cover the term of the license and are submitted at the time the application is filed.

TABLE 2—REVENUE REQUIREMENTS AND PRO-RATA FEES

Fee category	FY 2022 payment units	Yrs	FY 2021 revenue estimate	Pro-rated FY 2022 revenue requirement	Computed FY 2022 regulatory fee	Rounded FY 2022 reg. fee	Expected FY 2022 revenue
PLMRS (Exclusive Use)	750	10	75,000	187,500	25.00	25	187,500
PLMRS (Shared use)	12,500	10	990,000	1,250,000	10.00	10	1,250,000
Microwave	18,000	10	4,750,000	4,500,000	25.00	25	4,500,000
Marine (Ship)	6,900	10	922,500	1,035,000	15.00	15	1,035,500
Aviation (Aircraft)	4,200	10	390,000	420,000	10.00	10	420,000
Marine (Coast)	210	10	16,000	84,000	40.00	40	84,000
Aviation (Ground)	350	10	110,000	70,000	20.00	20	70,000
AM Class A [1]	62	1	290,745	326,635	5,268	5,270	326,740
AM Class B [1]	1,430	1	3,610,880	4,052,570	2,834	2,835	4,054,050
AM Class C [1]	808	1	1,291,125	1,450,902	1,796	1,795	1,450,360
AM Class D [1]	1,356	1	4,267,835	4,793,696	3,535	3,535	4,793,460
FM Classes A, B1 & C3 [1]	3,045	1	8,886,395	10,109,721	3,320	3,320	10,109,400
FM Classes B, C, C0, C1 & C2 [1]	3,118	1	11,100,080	12,379,377	3,970	3,970	12,378,460
AM Construction Permits [2]	5	1	3,660	3,450	690	690	3,450
FM Construction Permits [2]	16	1	58,850	19,360	1,210	1,210	19,360
Digital Television [5] (including Satellite TV)	3.283 billion population	1	25,416,380	28,896,824	.00880277	.008803	28,897,591
Digital TV Construction Permits [2]	4	1	20,400	20,840	5,210	5,210	20,840
LPTV/Class A/Translators FM Trans/Boosters	5,466	1	1,649,920	1,855,851	339.5	340	1,858,440
CARS Stations	135	1	233,250	229,890	1,702.9	1,705	230,175
Cable TV Systems, including IPTV & DBS	65,000,000	1	76,244,000	76,369,621	1.1484	1.15	76,475,000
Interstate Telecommunication Service Providers	$28,800,000,000	1	120,400,000	124,588,996	0.004326	0.004330	124,704,000
Toll Free Numbers	34,700,000	1	4,020,000	4,280,934	0.12337	0.12	4,164,000
CMRS Mobile Services (Cellular/Public Mobile)	509,000,000	1	75,600,000	72,687,506	0.1436	0.14	71,260,000
CMRS Messaging Services	1,500,000	1	136,000	120,000	0.0800	0.080	120,000
BRS/ [3]	1,225	1	756,250	716,625	585	585	716,625
LMDS	350	1	206,910	204,750	585	585	204,750
Per Gbps circuit Int'l Bearer Circuits	12,000	1	468,700	464,319	38.69	39	468,000
Terrestrial (Common & Non-Common) & Satellite (Common & Non-Common).							
Submarine Cable Providers (See chart at bottom of Table 3) [4].	64.438	1	8,839,554	8,822,058	136,909	136,910	8,822,138
Earth Stations	2,900	1	1,785,000	1,787,717	616.5	615	1,783,500
Space Stations (Geostationary)	141	1	17,177,685	17,143,881	121,588	121,590	17,144,190
Space Stations (Non-Geostationary, Other)	10	1	3,435,550	3,380,200	338,020	338,020	3,380,200
Space Stations (Non-Geostationary, Less Complex)	6	1	858,865	845,050	140,842	140,840	845,040
Space Stations (Non-Geostationary, Small Satellite)	5	1	0	60,720	12,144	12,145	60,725
Total Estimated Revenue to be Collected			373,920,077	383,225,896			381,836,994
Total Revenue Requirement			374,000,000	381,950,000			381,950,000
Difference			(79,923)	1,275,896			(113,006)

Notes on Table 2:

[1] The fee amounts listed in the column entitled "Rounded New FY 2022 Regulatory Fee" constitute a weighted average broadcast regulatory fee by class of service. The actual FY 2022 regulatory fees for AM/FM radio station are listed on a grid located at the end of Table 3.

[2] The AM and FM Construction Permit revenues and the Digital (VHF/UHF) Construction Permit revenues were adjusted, respectively, to set the regulatory fee to an amount no higher than the lowest licensed fee for that class of service. Reductions in the Digital (VHF/UHF) Construction Permit revenues, and in the AM and FM Construction Permit revenues, were offset by increases in the revenue totals for Digital television stations by market size, and in the AM and FM radio stations by class size and population served, respectively.

[3] The MDS/MMDS category was renamed Broadband Radio Service (BRS). *See Amendment of Parts 1, 21, 73, 74 and 101 of the Commission's Rules to Facilitate the Provision of Fixed and Mobile Broadband Access, Educational and Other Advanced Services in the 2150–2162 and 2500–2690 MHz Bands,* Report & Order, 69 FR 72020 (Dec. 10, 2004), and Further Notice of Proposed Rulemaking, 69 FR 72048 (Dec. 10, 2004), 19 FCC Rcd 14165, 14169, para. 6 (2004).

[4] The chart at the end of Table 3 lists the submarine cable bearer circuit regulatory fees (common and non-common carrier basis) that resulted from the adoption of the *Assessment and Collection of Regulatory Fees for Fiscal Year 2008,* Report and Order, 73 FR 50201(Aug. 26, 2008), and Further Notice of Proposed Rulemaking, 73 FR 50285 (Aug. 26, 2008), 24 FCC Rcd 6388 (2008) and *Assessment and Collection of Regulatory Fees for Fiscal Year 2008,* Second Report and Order, 74 FR 36948 (July 27, 2009), 24 FCC Rcd 4208 (2009). The Submarine Cable fee in Table 2 is a weighted average of the various fee payers in the chart at the end of Table 3.

[5] The actual digital television regulatory fees to be paid by call sign are identified in Table 7.

Regulatory fees for the categories shaded in gray are collected by the Commission in advance to cover the term of the license and are submitted at the time the application is filed.

TABLE 3—FY 2022 SCHEDULE OF REGULATORY FEES

Fee category	Annual regulatory fee (U.S. $s)
PLMRS (per license) (Exclusive Use) (47 CFR part 90)	25.
Microwave (per license) (47 CFR part 101)	25.
Marine (Ship) (per station) (47 CFR part 80)	15.
Marine (Coast) (per license) (47 CFR part 80)	40.
Rural Radio (47 CFR part 22) (previously listed under the Land Mobile category)	10.
PLMRS (Shared Use) (per license) (47 CFR part 90)	10.
Aviation (Aircraft) (per station) (47 CFR part 87)	10.
Aviation (Ground) (per license) (47 CFR part 87)	20.
CMRS Mobile/Cellular Services (per unit) (47 CFR parts 20, 22, 24, 27, 80, and 90) (Includes Non-Geographic telephone numbers).	.14.
CMRS Messaging Services (per unit) (47 CFR parts 20, 22, 24, and 90)	.08.
Broadband Radio Service (formerly MMDS/MDS) (per license) (47 CFR part 27)	585.
Local Multipoint Distribution Service (per call sign) (47 CFR part 101)	585.
AM Radio Construction Permits	690.
FM Radio Construction Permits	1,210.
AM and FM Broadcast Radio Station Fees	See Table Below.
Digital TV (47 CFR part 73) VHF and UHF Commercial Fee Factor	$.008803. See Table 7 for fee amounts due, also available at *https://www.fcc.gov/licensing-databases/fees/regulatory-fees.*
Digital TV Construction Permits	5,210.
Low Power TV, Class A TV, TV/FM Translators & FM Boosters (47 CFR part 74)	340.
CARS (47 CFR part 78)	1,705.
Cable Television Systems (per subscriber) (47 CFR part 76), Including IPTV	1.15.
Interstate Telecommunication Service Providers (per revenue dollar)	.00433.
Toll Free (per toll free subscriber) (47 CFR (f))	.12.
Earth Stations (47 CFR part 25)	615.
Space Stations (per operational station in geostationary orbit) (47 CFR part 25) also includes DBS Service (per operational station) (47 CFR part 100).	121,590.
Space Stations (per operational system in non-geostationary orbit) (47 CFR part 25) (Other)	338,020.
Space Stations (per operational system in non-geostationary orbit) (47 CFR part 25) (Less Complex)	140,840.
Space Stations (per license/call sign in non-geostationary orbit) (47 CFR part 25) (Small Satellite)	12,145.
International Bearer Circuits—Terrestrial/Satellites (per Gbps circuit)	39.
Submarine Cable Landing Licenses Fee (per cable system)	See Table Below.

FY 2022 RADIO STATION REGULATORY FEES

Population served	AM Class A	AM Class B	AM Class C	AM Class D	FM Classes A, B1 & C3	FM Classes B, C, C0, C1 & C2
<=25,000	$1,105	$795	$690	$760	$1,210	$1,380
25,001–75,000	1,660	1,195	1,035	1,140	1,815	2,070
75,001–150,000	2,485	1,790	1,555	1,710	2,725	3,105
150,001–500,000	3,735	2,685	2,330	2,570	4,090	4,665
500,001–1,200,000	5,590	4,025	3,490	3,845	6,125	6,985
1,200,001–3,000,000	8,400	6,040	5,245	5,775	9,195	10,490
3,000,001–6,000,000	12,585	9,055	7,860	8,655	13,780	15,720
>6,000,000	18,885	13,585	11,790	12,990	20,680	23,585

FY 2022 INTERNATIONAL BEARER CIRCUITS—SUBMARINE CABLE SYSTEMS

Submarine cable systems (capacity as of December 31, 2021)	Fee ratio (units)	FY 2021 regulatory fees
Less than 50 Gbps	.0625	$8,560
50 Gbps or greater, but less than 250 Gbps	.125	17,115
250 Gbps or greater, but less than 1,500 Gbps	.25	34,230
1,500 Gbps or greater, but less than 3,500 Gbps	.5	68,455
3,500 Gbps or greater, but less than 6,500 Gbps	1.0	136,910
6,500 Gbps or greater	2.0	273,820

In order to calculate individual service fees for FY 2022, we adjusted FY 2021 payment units for each service to more accurately reflect expected FY 2022 payment liabilities. We obtained our updated estimates through a variety of means and sources. For example, we used Commission licensee data bases, actual prior year payment records and industry and trade association projections, where available. The databases we consulted include our Universal Licensing System (ULS), International Bureau Filing System (IBFS), Consolidated Database System (CDBS), Licensing and Management System (LMS) and Cable Operations and Licensing System (COALS), as well as reports generated within the Commission such as the Wireless Telecommunications Bureau's *Numbering Resource Utilization Forecast.* Regulatory fee payment units are not all the same for all fee categories. For most fee categories, the term ''units'' reflect licenses or permits that have been issued, but for other fee categories, the term ''units'' reflect quantities such as subscribers, population counts, circuit counts, telephone numbers, and revenues.

We sought verification for these estimates from multiple sources and, in all cases, we compared FY 2022 estimates with actual FY 2021 payment units to ensure that our revised estimates were reasonable. Where appropriate, we adjusted and/or rounded our final estimates to take into consideration the fact that certain variables that impact on the number of payment units cannot yet be estimated with sufficient accuracy. These include an unknown number of waivers and/or exemptions that may occur in FY 2022 and the fact that, in many services, the number of actual licensees or station operators fluctuates from time to time due to economic, technical, or other reasons. When we note, for example, that our estimated FY 2022 payment units are based on FY 2021 actual payment units, it does not necessarily mean that our FY 2022 projection is exactly the same number as in FY 2021. We have either rounded the FY 2022 number or adjusted it slightly to account for these variables.

TABLE 4—SOURCES OF PAYMENT UNIT ESTIMATES FOR FY 2022

Fee category	Sources of payment unit estimates
Land Mobile (All), Microwave, Marine (Ship & Coast), Aviation (Aircraft & Ground), Domestic Public Fixed.	Based on Wireless Telecommunications Bureau (WTB) projections of new applications and renewals taking into consideration existing Commission licensee data bases. Aviation (Aircraft) and Marine (Ship) estimates have been adjusted to take into consideration the licensing of portions of these services on a voluntary basis.
CMRS Cellular/Mobile Services	Based on WTB projection reports, and FY 2021 payment data.
CMRS Messaging Services	Based on WTB reports, and FY 2021 payment data.
AM/FM Radio Stations	Based on CDBS data, adjusted for exemptions, and actual FY 2021 payment units.
Digital TV Stations (Combined VHF/UHF units)	Based on LMS data, fee rate adjusted for exemptions, and population figures are calculated based on individual station parameters.
AM/FM/TV Construction Permits	Based on CDBS data, adjusted for exemptions, and actual FY 2021 payment units.
LPTV, Translators and Boosters, Class A Television	Based on LMS data, adjusted for exemptions, and actual FY 2021 payment units.
BRS (formerly MDS/MMDS) LMDS	Based on WTB reports and actual FY 2021 payment units. Based on WTB reports and actual FY 2021 payment units.
Cable Television Relay Service (CARS) Stations	Based on data from Media Bureau's COALS database and actual FY 2021 payment units.
Cable Television System Subscribers, Including IPTV Subscribers.	Based on publicly available data sources for estimated subscriber counts, trend information from past payment data, and actual FY 2021 payment units.
Interstate Telecommunication Service Providers	Based on FCC Form 499–A worksheets due in April 2022, and any data assistance provided by the Wireline Competition Bureau.
Earth Stations	Based on International Bureau licensing data and actual FY 2021 payment units.
Space Stations (GSOs & NGSOs)	Based on International Bureau data reports and actual FY 2021 payment units.
International Bearer Circuits	Based on assistance provided by the International Bureau, any data submissions by licensees, adjusted as necessary, and actual FY 2021 payment units.
Submarine Cable Licenses	Based on International Bureau license information, and actual FY 2021 payment units.

TABLE 5

Factors, Measurements, and Calculations That Determine Station Signal Contours and Associated Population Coverages
AM Stations:
For stations with nondirectional daytime antennas, the theoretical radiation was used at all azimuths. For stations with directional daytime antennas, specific information on each day tower, including field ratio, phase, spacing, and orientation was retrieved, as well as the theoretical pattern root-mean-square of the radiation in all directions in the horizontal plane (RMS) figure (milliVolt per meter (mV/m) @1 km) for the antenna system. The standard, or augmented standard if pertinent, horizontal plane radiation pattern was calculated using techniques and methods specified in §§ 73.150 and 73.152 of the Commission's rules. Radiation values were calculated for each of 360 radials around the transmitter site. Next, estimated soil conductivity data was retrieved from a database representing the information in FCC Figure R3. Using the calculated horizontal radiation values, and the retrieved soil conductivity data, the distance to the principal community (5 mV/m) contour was predicted for each of the 360 radials. The resulting distance to principal community contours were used to form a geographical polygon. Population counting was accomplished by determining which 2010 block centroids were contained in the polygon. (A block centroid is the center point of a small area containing population as computed by the U.S. Census Bureau.) The sum of the population figures for all enclosed blocks represents the total population for the predicted principal community coverage area.
FM Stations:
The greater of the horizontal or vertical effective radiated power (ERP) (kW) and respective height above average terrain (HAAT) (m) combination was used. Where the antenna height above mean sea level (HAMSL) was available, it was used in lieu of the average HAAT figure to calculate specific HAAT figures for each of 360 radials under study. Any available directional pattern information was applied as well, to produce a radial-specific ERP figure. The HAAT and ERP figures were used in conjunction with the Field Strength (50–50) propagation curves specified in 47 CFR 73.313 of the Commission's rules to predict the distance to the principal community (70 dBu (decibel above 1 microVolt per meter) or 3.17 mV/m) contour for each of the 360 radials. The resulting distance to principal community contours were used to form a geographical polygon. Population counting was accomplished by determining which 2010 block centroids were contained in the polygon. The sum of the population figures for all enclosed blocks represents the total population for the predicted principal community coverage area.

TABLE 6—SATELLITE CHARTS FOR FY 2022 REGULATORY FEES

Licensee	Call sign	Satellite name	Type
U.S.-Licensed Space Stations			
DIRECTV Enterprises, LLC	S2922	SKY–B1	GSO.
DIRECTV Enterprises, LLC	S2640	DIRECTV T11	GSO.
DIRECTV Enterprises, LLC	S2711	DIRECTV RB–1	GSO.
DIRECTV Enterprises, LLC	S2632	DIRECTV T8	GSO.
DIRECTV Enterprises, LLC	S2669	DIRECTV T9S	GSO.
DIRECTV Enterprises, LLC	S2641	DIRECTV T10	GSO.
DIRECTV Enterprises, LLC	S2797	DIRECTV T12	GSO.
DIRECTV Enterprises, LLC	S2930	DIRECTV T15	GSO.
DIRECTV Enterprises, LLC	S2673	DIRECTV T5	GSO.
DIRECTV Enterprises, LLC	S2133	SPACEWAY 2	GSO.
DIRECTV Enterprises, LLC	S3039	DIRECTV T16	GSO.
DISH Operating L.L.C	S2931	ECHOSTAR 18	GSO.
DISH Operating L.L.C	S2738	ECHOSTAR 11	GSO.
DISH Operating L.L.C	S2694	ECHOSTAR 10	GSO.
DISH Operating L.L.C	S2740	ECHOSTAR 7	GSO.
DISH Operating L.L.C	S2790	ECHOSTAR 14	GSO.
EchoStar Satellite Operating Corporation	S2811	ECHOSTAR 15	GSO.
EchoStar Satellite Operating Corporation	S2844	ECHOSTAR 16	GSO.
EchoStar Satellite Services L.L.C	S2179	ECHOSTAR 9	GSO.
ES 172 LLC	S2610	EUTELSAT 174A	GSO.
ES 172 LLC	S3021	EUTELSAT 172B	GSO
Horizon–3 Satellite LLC	S2947	HORIZONS–3e	GSO.
Hughes Network Systems, LLC	S2663	SPACEWAY 3	GSO.
Hughes Network Systems, LLC	S2834	ECHOSTAR 19	GSO.
Hughes Network Systems, LLC	S2753	ECHOSTAR XVII	GSO.
Intelsat License LLC/ViaSat, Inc	S2160	GALAXY 28	GSO.
Intelsat License LLC, Debtor-in-Possession	S2414	INTELSAT 10–02	GSO.
Intelsat License LLC, Debtor-in-Possession	S2972	INTELSAT 37e	GSO.
Intelsat License LLC, Debtor-in-Possession	S2854	NSS–7	GSO.
Intelsat License LLC, Debtor-in-Possession	S2409	INELSAT 905	GSO.
Intelsat License LLC, Debtor-in-Possession	S2405	INTELSAT 901	GSO.
Intelsat License LLC, Debtor-in-Possession	S2408	INTELSAT 904	GSO.
Intelsat License LLC, Debtor-in-Possession	S2804	INTELSAT 25	GSO.
Intelsat License LLC, Debtor-in-Possession	S2959	INTELSAT 35e	GSO.
Intelsat License LLC, Debtor-in-Possession	S2237	INTELSAT 11	GSO.
Intelsat License LLC, Debtor-in-Possession	S2785	INTELSAT 14	GSO.
Intelsat License LLC, Debtor-in-Possession	S2380	INTELSAT 9	GSO.
Intelsat License LLC, Debtor-in-Possession	S2831	INTELSAT 23	GSO.
Intelsat License LLC, Debtor-in-Possession	S2915	INTELSAT 34	GSO.
Intelsat License LLC, Debtor-in-Possession	S2863	INTELSAT 21	GSO.
Intelsat License LLC, Debtor-in-Possession	S2750	INTELSAT 16	GSO.
Intelsat License LLC, Debtor-in-Possession	S2715	GALAXY 17	GSO.

TABLE 6—SATELLITE CHARTS FOR FY 2022 REGULATORY FEES—Continued

Licensee	Call sign	Satellite name	Type
Intelsat License LLC, Debtor-in-Possession	S2154	GALAXY 25	GSO.
Intelsat License LLC, Debtor-in-Possession	S2253	GALAXY 11	GSO.
Intelsat License LLC, Debtor-in-Possession	S2381	GALAXY 3C	GSO.
Intelsat License LLC, Debtor-in-Possession	S2887	INTELSAT 30	GSO.
Intelsat License LLC, Debtor-in-Possession	S2924	INTELSAT 31	GSO.
Intelsat License LLC, Debtor-in-Possession	S2647	GALAXY 19	GSO.
Intelsat License LLC, Debtor-in-Possession	S2687	GALAXY 16	GSO.
Intelsat License LLC, Debtor-in-Possession	S2733	GALAXY 18	GSO.
Intelsat License LLC, Debtor-in-Possession	S2385	GALAXY 14	GSO.
Intelsat License LLC, Debtor-in-Possession	S2386	GALAXY 13	GSO.
Intelsat License LLC, Debtor-in-Possession	S2422	GALAXY 12	GSO.
Intelsat License LLC, Debtor-in-Possession	S2387	GALAXY 15	GSO.
Intelsat License LLC, Debtor-in-Possession	S2704	INTELSAT 5	GSO.
Intelsat License LLC, Debtor-in-Possession	S2817	INTELSAT 18	GSO.
Intelsat License LLC, Debtor-in-Possession	S2960	JCSAT–RA	GSO.
Intelsat License LLC, Debtor-in-Possession	S2850	INTELSAT 19	GSO.
Intelsat License LLC, Debtor-in-Possession	S2368	INTELSAT 1R	GSO.
Intelsat License LLC, Debtor-in-Possession	S2988	TELKOM–2	GSO.
Intelsat License LLC, Debtor-in-Possession	S2789	INTELSAT 15	GSO.
Intelsat License LLC, Debtor-in-Possession	S2423	HORIZONS 2	GSO.
Intelsat License LLC, Debtor-in-Possession	S2846	INTELSAT 22	GSO.
Intelsat License LLC, Debtor-in-Possession	S2847	INTELSAT 20	GSO.
Intelsat License LLC, Debtor-in-Possession	S2948	INTELSAT 36	GSO.
Intelsat License LLC, Debtor-in-Possession	S2814	INTELSAT 17	GSO.
Intelsat License LLC, Debtor-in-Possession	S2410	INTELSAT 906	GSO.
Intelsat License LLC, Debtor-in-Possession	S2406	INTELSAT 902	GSO.
Intelsat License LLC, Debtor-in-Possession	S2939	INTELSAT 33e	GSO.
Intelsat License LLC, Debtor-in-Possession	S2382	INTELSAT 10	GSO.
Intelsat License LLC, Debtor-in-Possession	S2751	NEW DAWN	GSO.
Intelsat License LLC, Debtor-in-Possession	S3023	INTELSAT 39	GSO.
Leidos, Inc	S2371	LM–RPS2	GSO.
Ligado Networks Subsidiary, LLC	S2358	SKYTERRA–1	GSO.
Ligado Networks Subsidiary, LLC	AMSC–1	MSAT–2	GSO.
Novavision Group, Inc	S2861	DIRECTV KU–79W	GSO.
Satellite CD Radio LLC	S2812	FM–6	GSO.
SES Americom, Inc	S2415	NSS–10	GSO.
SES Americom, Inc	S2162	AMC–3	GSO.
SES Americom, Inc	S2347	AMC–6	GSO.
SES Americom, Inc	S2826	SES–2	GSO.
SES Americom, Inc	S2807	SES–1	GSO.
SES Americom, Inc	S2892	SES–3	GSO.
SES Americom, Inc	S2180	AMC–15	GSO.
SES Americom, Inc	S2445	AMC–1	GSO.
SES Americom, Inc	S2135	AMC–4	GSO.
SES Americom, Inc	S2713	AMC–18	GSO.
SES Americom, Inc	S2433	AMC–11	GSO.
SES Americom, Inc./Alascom, Inc	S2379	AMC–8	GSO.
Sirius XM Radio Inc	S2710	FM–5	GSO.
Sirius XM Radio Inc	S3033	XM–7	GSO.
Sirius XM Radio Inc	S3034	XM–8	GSO.
Skynet Satellite Corporation	S2933	TELSTAR 12V	GSO.
Skynet Satellite Corporation	S2357	TELSTAR 11N	GSO.
ViaSat, Inc	S2747	VIASAT–1	GSO.
XM Radio LLC	S2617	XM–3	GSO.
XM Radio LLC	S2616	XM–4	GSO.

Licensee	Call sign	Satellite common name	Satellite type
Non-U.S.-Licensed Space Stations—Market Access Through Petition for Declaratory Ruling			
ABS Global Ltd	S2987	ABS–3A	GSO.
DBSD Services Ltd	S2651	DBSD G1	GSO.
Empresa Argentina de Soluciones Satelitales S.A	S2956	ARSAT–2	GSO.
European Telecommunications Satellite Organization	S3031	EUTELSAT 133 WEST A	GSO.
Eutelsat S.A	S3056	EUTELSAT 8 WEST B	GSO.
Gamma Acquisition L.L.C	S2633	TerreStar 1	GSO.
Hispamar Satélites, S.A	S2793	AMAZONAS–2	GSO.
Hispamar Satélites, S.A	S2886	AMAZONAS–3	GSO.
Hispasat, S.A	S2969	HISPASAT 30W–6	GSO.
Inmarsat PLC	S2932	Inmarsat-4 F3	GSO.

Licensee	Call sign	Satellite common name	Satellite type
Inmarsat PLC	S2949	Inmarsat-3 F5	GSO.
Intelsat License LLC	S3058	HISPASAT 143W–1	GSO.
New Skies Satellites B.V	S2756	NSS–9	GSO.
New Skies Satellites B.V	S2870	SES–6	GSO.
New Skies Satellites B.V	S3048	NSS–6	GSO.
New Skies Satellites B.V	S2828	SES–4	GSO.
New Skies Satellites B.V	S2950	SES–10	GSO.
Satelites Mexicanos, S.A. de C.V	S2695	EUTELSAT 113 WEST A	GSO.
Satelites Mexicanos, S.A. de C.V	S2926	EUTELSAT 117 WEST B	GSO.
Satelites Mexicanos, S.A. de C.V	S2938	EUTELSAT 115 WEST B	GSO.
Satelites Mexicanos, S.A. de C.V	S2873	EUTELSAT 117 WEST A	GSO.
SES Satellites (Gibraltar) Ltd	S2676	AMC 21	GSO.
SES Americom, Inc	S3037	NSS–11	GSO.
SES Americom, Inc	S2964	SES–11	GSO.
SES DTH do Brasil Ltda	S2974	SES–14	GSO.
SES Satellites (Gibraltar) Ltd	S2951	SES–15	GSO.
Embratel Tvsat Telecommunicacoes S.A	S2677	STAR ONE C1	GSO.
Embratel Tvsat Telecommunicacoes S.A	S2678	STAR ONE C2	GSO.
Embratel Tvsat Telecommunicacoes S.A	S2845	STAR ONE C3	GSO
Telesat Brasil Capacidade de Satelites Ltda	S2821	ESTRELA DO SUL 2	GSO.
Telesat Canada	S2674	ANIK F1R	GSO.
Telesat Canada	S2703	ANIK F3	GSO.
Telesat Canada	S2646/S2472	ANIK F2	GSO.
Telesat International Ltd	S2955	TELSTAR 19 VANTAGE	GSO.
Viasat, Inc	S2902	VIASAT–2	GSO.

ITU name (if available)	Common name	Call sign	GSO/NGSO
Non-U.S.-Licensed Space Stations—Market Access Through Earth Station Licenses			
APSTAR VI	APSTAR 6	M292090	GSO.
AUSSAT B 152E	OPTUS D2	M221170	GSO.
CAN–BSS3 and CAN–BSS	ECHOSTAR 23	SM1987/ SM2975.	GSO.
Ciel Satellite Group	Ciel-2	E050029	GSO.
Eutelsat 65 West A	Eutelsat 65 West A	E160081	GSO.
INMARSAT 3F3	INMARSAT 3F3	E000284	GSO.
INMARSAT 4F1	INMARSAT 4F1	KA25	GSO.
INMARSAT 5F2	INMARSAT 5F2	E120072	GSO.
INMARSAT 5F3	INMARSAT 5F3	E150028	GSO.
JCSAT–2B	JCSAT–2B	M174163	GSO.
NIMIQ 5	NIMIQ 5	E080107	GSO.
QUETZSAT–1(MEX)	QUETZSAT–1	NUS1101	GSO.
Superbird C2	Superbird C2	M334100	GSO.
WILDBLUE–1	WILDBLUE–1	E040213	GSO.
Yamal 300K	Yamal 300K	M174162	GSO.

ITU name (if available)	Common name	Call sign	NGSO
Non-Geostationary Space Stations (NGSO) U.S.-Licensed NGSO Systems			
ORBCOMM License Corp	ORBCOMM	S2103	Other.
Iridium Constellation LLC	IRIDIUM	S2110	Other.
Space Exploration Holdings, LLC	SPACEX Ku/Ka-Band	S2983/S3018	Other.
Swarm Technologies	SWARM	S3041	Other.
Planet Labs	Flock/Skysats	S2912	Less Complex.
Maxar License	WorldView 1,2 & 3, GeoEye-1	S2129/S2348	Less Complex.
BlackSky Global	Global	S3032	Less Complex.
Astro Digital U.S., Inc	LANDMAPPER	S3014	Less Complex.
Hawkeye 360	HE360	S3042	Less Complex.
Non-U.S.-Licensed NGSO Systems—Market Access Through Petition for Declaratory Ruling			
Telesat Canada	TELESAT Ku/Ka-Band	S2976	Other.
Kepler Communications, Inc	KEPLER	S2981	Other.
WorldVu Satellites Ltd	ONEWEB	S2963	Other.
Myriota Pty. Ltd	MYRIOTA	S3047	Other.
O3b Ltd	O3b	S2935	Other.

ITU name (if available)	Common name	Call sign	NGSO
NGSO Systems That Are Partly U.S.-Licensed and Partly Non-U.S.-Licensed With Market Access Through Petition for Declaratory Ruling			
Globalstar License LLC	GLOBALSTAR	S2115	Other.
Spire Global	LEMUR & MINAS	S2946/S3045	Less Complex.
NGSO Systems Licensed Under the Streamlined Small Satellite Rules			
Capella Space Corp	Capella-2, Capella-3, Capella-4	S3073	Small Satellite.
Capella Space Corp	Capella-5, Capella-6	S3080	Small Satellite.
Loft Orbital Solutions Inc	YAM–2	S3052	Small Satellite.
Loft Orbital Solutions Inc	YAM–3	S3072	Small Satellite.
R2 Space, Inc	XR–1	S3067	Small Satellite.

TABLE 7—FY 2022 FULL-SERVICE BROADCAST TELEVISION STATIONS BY CALL SIGN

Facility Id.	Call sign	Service area population	Terrain limited population	Terrain limited fee amount
3246	KAAH–TV	955,391	879,906	$7,746
18285	KAAL	589,502	568,169	5,002
11912	KAAS–TV	220,262	219,922	1,936
56528	KABB	2,474,296	2,456,689	21,626
282	KABC–TV	17,540,791	16,957,292	149,275
1236	KACV–TV	372,627	372,330	3,278
33261	KADN–TV	877,965	877,965	7,729
8263	KAEF–TV	138,085	122,808	1,081
2728	KAET	4,217,217	4,184,386	36,835
2767	KAFT	1,204,376	1,122,928	9,885
62442	KAID	711,035	702,721	6,186
4145	KAII–TV	188,810	165,396	1,456
67494	KAIL	1,947,635	1,914,765	16,856
13988	KAIT	861,149	845,812	7,446
40517	KAJB	383,886	383,195	3,373
65522	KAKE	803,937	799,254	7,036
804	KAKM	380,240	379,105	3,337
148	KAKW–DT	2,615,956	2,531,813	22,288
51598	KALB–TV	943,307	942,043	8,293
51241	KALO	954,557	910,409	8,014
40820	KAMC	391,526	391,502	3,446
8523	KAMR–TV	366,476	366,335	3,225
65301	KAMU–TV	346,892	342,455	3,015
2506	KAPP	319,797	283,944	2,500
3658	KARD	703,234	700,887	6,170
23079	KARE	3,924,944	3,907,483	34,398
33440	KARK–TV	1,212,038	1,196,196	10,530
37005	KARZ–TV	1,113,486	1,095,224	9,641
32311	KASA–TV	1,161,837	1,119,457	9,855
41212	KASN	1,175,627	1,159,721	10,209
7143	KASW	4,174,437	4,160,497	36,625
55049	KASY–TV	1,145,133	1,100,391	9,687
33471	KATC	1,348,897	1,348,897	11,874
13813	KATN	97,466	97,128	855
21649	KATU	3,030,547	2,881,993	25,370
33543	KATV	1,257,777	1,234,933	10,871
50182	KAUT–TV	1,637,333	1,636,330	14,405
21488	KAUU	381,413	380,355	3,348
6864	KAUZ–TV	381,671	379,435	3,340
73101	KAVU–TV	319,618	319,484	2,812
49579	KAWB	186,919	186,845	1,645
49578	KAWE	136,033	133,937	1,179
58684	KAYU–TV	809,464	750,766	6,609
29234	KAZA–TV	14,973,535	13,810,130	121,571
17433	KAZD	6,776,778	6,774,172	59,633
1151	KAZQ	1,097,010	1,084,327	9,545
35811	KAZT–TV	436,925	359,273	3,163
4148	KBAK–TV	1,510,400	1,263,910	11,126
16940	KBCA	479,260	479,219	4,219
53586	KBCB	1,256,193	1,223,883	10,774
69619	KBCW	8,227,562	7,375,199	64,924
22685	KBDI–TV	4,042,177	3,683,394	32,425
56384	KBEH	17,736,497	17,695,306	155,772

TABLE 7—FY 2022 FULL-SERVICE BROADCAST TELEVISION STATIONS BY CALL SIGN—Continued

Facility Id.	Call sign	Service area population	Terrain limited population	Terrain limited fee amount
65395	KBFD–DT	953,207	834,341	7,345
169030	KBGS–TV	159,269	156,802	1,380
61068	KBHE–TV	140,860	133,082	1,172
48556	KBIM–TV	205,701	205,647	1,810
29108	KBIN–TV	912,921	911,725	8,026
33658	KBJR–TV	275,585	271,298	2,388
83306	KBLN–TV	297,384	134,927	1,188
63768	KBLR	1,964,979	1,915,861	16,865
53324	KBME–TV	123,571	123,485	1,087
10150	KBMT	743,009	742,369	6,535
22121	KBMY	119,993	119,908	1,056
49760	KBOI–TV	715,191	708,374	6,236
55370	KBRR	149,869	149,868	1,319
66414	KBSD–DT	155,012	154,891	1,364
66415	KBSH–DT	102,781	100,433	884
19593	KBSI	756,501	754,722	6,644
66416	KBSL–DT	49,814	48,483	427
4939	KBSV	1,352,166	1,262,708	11,116
62469	KBTC–TV	3,697,981	3,621,965	31,884
61214	KBTV–TV	734,008	734,008	6,461
6669	KBTX–TV	4,404,648	4,401,048	38,742
35909	KBVO	1,498,015	1,312,360	11,553
58618	KBVU	135,249	120,827	1,064
6823	KBYU–TV	2,389,548	2,209,060	19,446
33756	KBZK	123,523	109,131	961
21422	KCAL–TV	17,499,483	16,889,157	148,675
11265	KCAU–TV	714,315	706,224	6,217
14867	KCBA	3,088,394	2,369,803	20,861
27507	KCBD	414,804	414,091	3,645
9628	KCBS–TV	17,853,152	16,656,778	146,630
49750	KCBY–TV	89,156	73,211	644
33710	KCCI	1,109,952	1,102,514	9,705
9640	KCCW–TV	284,280	276,935	2,438
63158	KCDO–TV	2,798,103	2,650,225	23,330
62424	KCDT	698,389	657,101	5,784
83913	KCEB	417,491	417,156	3,672
57219	KCEC	3,831,192	3,613,287	31,808
10245	KCEN–TV	1,795,767	1,757,018	15,467
13058	KCET	16,875,019	15,402,588	135,589
18079	KCFW–TV	177,697	140,192	1,234
132606	KCGE–DT	123,930	123,930	1,091
60793	KCHF	1,118,671	1,085,205	9,553
33722	KCIT	382,477	381,818	3,361
62468	KCKA	953,680	804,362	7,081
41969	KCLO–TV	138,413	132,157	1,163
47903	KCNC–TV	3,794,400	3,541,089	31,172
71586	KCNS	8,270,858	7,381,656	64,981
33742	KCOP–TV	17,386,133	16,647,708	146,550
19117	KCOS	1,014,396	1,014,205	8,928
63165	KCOY–TV	664,655	459,468	4,045
33894	KCPQ	4,439,875	4,312,133	37,960
53843	KCPT	2,507,879	2,506,224	22,062
33875	KCRA–TV	10,612,483	6,500,774	57,226
9719	KCRG–TV	1,136,762	1,107,130	9,746
60728	KCSD–TV	273,553	273,447	2,407
59494	KCSG	174,814	164,765	1,450
33749	KCTS–TV	4,177,824	4,115,603	36,230
41230	KCTV	2,547,456	2,545,645	22,409
58605	KCVU	684,900	674,585	5,938
10036	KCWC–DT	44,216	39,439	347
64444	KCWE	2,459,924	2,458,302	21,640
51502	KCWI–TV	1,043,811	1,042,642	9,178
42008	KCWO–TV	50,707	50,685	446
166511	KCWV	207,398	207,370	1,825
24316	KCWX	3,961,268	3,954,787	34,814
68713	KCWY–DT	80,904	80,479	708
22201	KDAF	6,648,507	6,645,226	58,498
33764	KDBC–TV	1,015,564	1,015,162	8,936
79258	KDCK	43,088	43,067	379
166332	KDCU–DT	753,204	753,190	6,630
38375	KDEN–TV	3,376,799	3,351,182	29,500

TABLE 7—FY 2022 FULL-SERVICE BROADCAST TELEVISION STATIONS BY CALL SIGN—Continued

Facility Id.	Call sign	Service area population	Terrain limited population	Terrain limited fee amount
17037	KDFI	6,684,439	6,682,487	58,826
33770	KDFW	6,659,312	6,657,023	58,602
29102	KDIN–TV	1,088,376	1,083,845	9,541
25454	KDKA–TV	3,611,796	3,450,690	30,376
60740	KDKF	71,413	64,567	568
4691	KDLH	263,422	260,394	2,292
41975	KDLO–TV	208,354	208,118	1,832
55379	KDLT–TV	639,284	628,281	5,531
55375	KDLV–TV	96,873	96,620	851
25221	KDMD	375,328	373,408	3,287
78915	KDMI	1,141,990	1,140,939	10,044
56524	KDNL–TV	2,987,219	2,982,311	26,253
24518	KDOC–TV	17,503,793	16,701,233	147,021
1005	KDOR–TV	1,112,060	1,108,556	9,759
60736	KDRV	519,706	440,002	3,873
61064	KDSD–TV	64,314	59,635	525
53329	KDSE	42,896	41,432	365
56527	KDSM–TV	1,096,220	1,095,478	9,643
49326	KDTN	6,602,327	6,600,186	58,101
83491	KDTP	26,564	24,469	215
33778	KDTV–DT	7,959,349	7,129,638	62,762
67910	KDTX–TV	6,680,738	6,679,424	58,799
126	KDVR	3,644,912	3,521,884	31,003
18084	KECI–TV	211,745	193,803	1,706
51208	KECY–TV	399,372	394,379	3,472
58408	KEDT	513,683	513,683	4,522
55435	KEET	177,313	159,960	1,408
37103	KEKE	97,959	94,560	832
41983	KELO–TV	705,364	646,126	5,688
34440	KEMO–TV	8,270,858	7,381,656	64,981
2777	KEMV	619,889	559,135	4,922
26304	KENS	2,544,094	2,529,382	22,266
63845	KENV–DT	47,220	40,677	358
18338	KENW	87,017	87,017	766
50591	KEPB–TV	576,964	523,655	4,610
56029	KEPR–TV	453,259	433,260	3,814
49324	KERA–TV	6,681,083	6,677,852	58,785
40878	KERO–TV	1,285,357	1,164,979	10,255
61067	KESD–TV	166,018	159,195	1,401
25577	KESQ–TV	1,334,172	572,057	5,036
50205	KETA–TV	1,702,441	1,688,227	14,861
62182	KETC	2,913,924	2,911,313	25,628
37101	KETD	3,323,570	3,285,231	28,920
2768	KETG	426,883	409,511	3,605
12895	KETH–TV	6,088,821	6,088,677	53,599
55643	KETK–TV	1,031,567	1,030,122	9,068
2770	KETS	1,185,111	1,166,796	10,271
53903	KETV	1,355,714	1,350,740	11,891
92872	KETZ	526,890	523,877	4,612
68853	KEYC–TV	544,900	531,079	4,675
33691	KEYE–TV	2,732,257	2,652,529	23,350
60637	KEYT–TV	1,419,564	1,239,577	10,912
83715	KEYU	339,348	339,302	2,987
34406	KEZI	1,113,171	1,065,880	9,383
34412	KFBB–TV	93,519	91,964	810
125	KFCT	795,114	788,747	6,943
51466	KFDA–TV	385,064	383,977	3,380
22589	KFDM	732,665	732,588	6,449
65370	KFDX–TV	381,703	381,318	3,357
49264	KFFV	4,020,926	3,987,153	35,099
12729	KFFX–TV	409,952	403,692	3,554
83992	KFJX	515,708	505,647	4,451
42122	KFMB–TV	3,947,735	3,699,981	32,571
53321	KFME	393,045	392,472	3,455
74256	KFNB	80,382	79,842	703
21613	KFNE	54,988	54,420	479
21612	KFNR	10,988	10,965	97
66222	KFOR–TV	1,616,459	1,615,614	14,222
33716	KFOX–TV	1,023,999	1,018,549	8,966
41517	KFPH–DT	347,579	282,838	2,490
81509	KFPX–TV	963,969	963,846	8,485

TABLE 7—FY 2022 FULL-SERVICE BROADCAST TELEVISION STATIONS BY CALL SIGN—Continued

Facility Id.	Call sign	Service area population	Terrain limited population	Terrain limited fee amount
31597	KFQX	186,473	163,637	1,440
59013	KFRE–TV	1,721,275	1,705,484	15,013
51429	KFSF–DT	7,348,828	6,528,430	57,470
66469	KFSM–TV	906,728	884,919	7,790
8620	KFSN–TV	1,836,607	1,819,585	16,018
29560	KFTA–TV	818,859	809,173	7,123
83714	KFTC	61,990	61,953	545
60537	KFTH–DT	6,080,688	6,080,373	53,526
60549	KFTR–DT	17,560,679	16,305,726	143,539
61335	KFTS	74,936	65,126	573
81441	KFTU–DT	113,876	109,731	966
34439	KFTV–DT	1,794,984	1,779,917	15,669
664	KFVE	82,902	73,553	647
592	KFVS–TV	895,871	873,777	7,692
29015	KFWD	6,666,428	6,660,565	58,633
35336	KFXA	875,538	874,070	7,694
17625	KFXB–TV	373,280	368,466	3,244
70917	KFXK–TV	934,043	931,791	8,203
84453	KFXL–TV	862,531	854,678	7,524
56079	KFXV	1,225,732	1,225,732	10,790
41427	KFYR–TV	130,881	128,301	1,129
25685	KGAN	1,083,213	1,057,597	9,310
34457	KGBT–TV	1,239,001	1,238,870	10,906
7841	KGCW	949,575	945,476	8,323
24485	KGEB	1,186,225	1,150,201	10,125
34459	KGET–TV	917,927	874,332	7,697
53320	KGFE	114,564	114,564	1,009
7894	KGIN	230,535	228,338	2,010
83945	KGLA–DT	1,645,641	1,645,641	14,487
34445	KGMB	953,398	851,088	7,492
58608	KGMC	1,936,675	1,914,168	16,850
36914	KGMD–TV	94,323	93,879	826
36920	KGMV	193,564	162,230	1,428
10061	KGNS–TV	267,236	259,548	2,285
34470	KGO–TV	8,637,074	7,929,294	69,802
56034	KGPE	1,699,131	1,682,082	14,807
81694	KGPX–TV	685,626	624,955	5,501
25511	KGTF	161,885	160,568	1,413
40876	KGTV	3,960,667	3,682,219	32,415
36918	KGUN–TV	1,398,527	1,212,484	10,673
34874	KGW	3,026,617	2,878,510	25,340
63177	KGWC–TV	80,475	80,009	704
63162	KGWL–TV	38,125	38,028	335
63166	KGWN–TV	469,467	440,388	3,877
63170	KGWR–TV	51,315	50,957	449
4146	KHAW–TV	95,204	94,851	835
60353	KHBS	631,770	608,052	5,353
27300	KHCE–TV	2,353,883	2,348,391	20,673
26431	KHET	959,060	944,568	8,315
21160	KHGI–TV	233,973	229,173	2,017
36917	KHII–TV	953,895	851,585	7,497
29085	KHIN	1,041,244	1,039,383	9,150
17688	KHME	181,345	179,706	1,582
47670	KHMT	175,601	170,957	1,505
47987	KHNE–TV	203,931	202,944	1,787
34867	KHNL	953,398	851,088	7,492
60354	KHOG–TV	765,360	702,984	6,188
4144	KHON–TV	953,207	886,431	7,803
34529	KHOU	6,083,336	6,081,785	53,538
4690	KHQA–TV	318,469	316,134	2,783
34537	KHQ–TV	822,371	774,821	6,821
30601	KHRR	1,227,847	1,166,890	10,272
34348	KHSD–TV	188,735	185,202	1,630
24508	KHSL–TV	625,904	608,850	5,360
69677	KHSV	2,059,794	2,020,045	17,782
64544	KHVO	94,226	93,657	824
23394	KIAH	6,099,694	6,099,297	53,692
34564	KICU–TV	8,233,041	7,174,316	63,156
56028	KIDK	305,509	302,535	2,663
58560	KIDY	116,614	116,596	1,026
53382	KIEM–TV	174,390	160,801	1,416

TABLE 7—FY 2022 FULL-SERVICE BROADCAST TELEVISION STATIONS BY CALL SIGN—Continued

Facility Id.	Call sign	Service area population	Terrain limited population	Terrain limited fee amount
66258	KIFI–TV	324,422	320,118	2,818
16950	KIFR	2,180,045	2,160,460	19,019
10188	KIII	569,864	566,796	4,990
29095	KIIN	1,365,215	1,335,707	11,758
34527	KIKU	953,896	850,963	7,491
63865	KILM	17,256,205	15,804,489	139,127
56033	KIMA–TV	308,604	260,593	2,294
66402	KIMT	654,083	643,384	5,664
67089	KINC	2,002,066	1,920,903	16,910
34847	KING–TV	4,074,288	4,036,926	35,537
51708	KINT–TV	1,015,582	1,015,274	8,937
26249	KION–TV	2,400,317	855,808	7,534
62427	KIPT	171,405	170,455	1,501
66781	KIRO–TV	4,058,101	4,030,968	35,485
62430	KISU–TV	311,827	307,651	2,708
12896	KITU–TV	712,362	712,362	6,271
64548	KITV	953,207	839,906	7,394
59255	KIVI–TV	710,819	702,619	6,185
47285	KIXE–TV	467,518	428,118	3,769
13792	KJJC–TV	82,749	81,865	721
14000	KJLA	17,929,100	16,794,896	147,845
20015	KJNP–TV	98,403	98,097	864
53315	KJRE	16,187	16,170	142
59439	KJRH–TV	1,416,108	1,397,311	12,301
55364	KJRR	45,515	44,098	388
7675	KJTL	379,594	379,263	3,339
55031	KJTV–TV	406,283	406,260	3,576
13814	KJUD	31,229	30,106	265
36607	KJZZ–TV	2,388,965	2,209,183	19,447
83180	KKAI	953,400	919,742	8,096
58267	KKAP	957,786	923,172	8,127
24766	KKCO	206,018	172,628	1,520
35097	KKJB	629,939	624,784	5,500
22644	KKPX–TV	7,588,288	6,758,490	59,495
35037	KKTV	2,892,126	2,478,864	21,821
35042	KLAS–TV	2,094,297	1,940,030	17,078
52907	KLAX–TV	367,212	366,839	3,229
3660	KLBK–TV	387,783	387,743	3,413
65523	KLBY	31,102	31,096	274
38430	KLCS	16,875,019	15,402,588	135,589
77719	KLCW–TV	381,889	381,816	3,361
51479	KLDO–TV	250,832	250,832	2,208
37105	KLEI	175,045	138,087	1,216
56032	KLEW–TV	164,908	148,256	1,305
35059	KLFY–TV	1,355,890	1,355,409	11,932
54011	KLJB	1,027,104	1,012,309	8,911
11264	KLKN	1,161,979	1,122,111	9,878
52593	KLML	270,089	218,544	1,924
47975	KLNE–TV	123,324	123,246	1,085
38590	KLPA–TV	414,699	414,447	3,648
38588	KLPB–TV	749,053	749,053	6,594
749	KLRN	2,374,472	2,353,440	20,717
11951	KLRT–TV	1,171,678	1,152,541	10,146
8564	KLRU	2,614,658	2,575,518	22,672
8322	KLSR–TV	564,415	508,157	4,473
31114	KLST	199,067	169,551	1,493
24436	KLTJ	6,034,131	6,033,867	53,116
38587	KLTL–TV	423,574	423,574	3,729
38589	KLTM–TV	694,280	688,915	6,065
38591	KLTS–TV	947,141	944,257	8,312
68540	KLTV	1,069,690	1,051,361	9,255
12913	KLUJ–TV	1,195,751	1,195,751	10,526
57220	KLUZ–TV	1,079,718	1,019,302	8,973
11683	KLVX	2,044,150	1,936,083	17,043
82476	KLWB	1,065,748	1,065,748	9,382
40250	KLWY	541,043	538,231	4,738
64551	KMAU	213,060	188,953	1,663
51499	KMAX–TV	10,767,605	7,132,240	62,785
65686	KMBC–TV	2,506,035	2,504,622	22,048
35183	KMCB	69,357	66,203	583
41237	KMCC	2,064,592	2,010,262	17,696

TABLE 7—FY 2022 FULL-SERVICE BROADCAST TELEVISION STATIONS BY CALL SIGN—Continued

Facility Id.	Call sign	Service area population	Terrain limited population	Terrain limited fee amount
42636	KMCI–TV	2,429,392	2,428,626	21,379
38584	KMCT–TV	267,004	266,880	2,349
22127	KMCY	71,797	71,793	632
162016	KMDE	35,409	35,401	312
26428	KMEB	221,810	203,470	1,791
39665	KMEG	708,748	704,130	6,198
35123	KMEX–DT	17,628,354	16,318,720	143,654
40875	KMGH–TV	3,815,224	3,574,344	31,465
35131	KMID	383,449	383,439	3,375
16749	KMIR–TV	2,760,914	730,764	6,433
63164	KMIZ	532,025	530,008	4,666
53541	KMLM–DT	293,290	293,290	2,582
52046	KMLU	711,951	708,107	6,233
47981	KMNE–TV	47,232	44,189	389
24753	KMOH–TV	199,885	184,283	1,622
4326	KMOS–TV	804,745	803,129	7,070
41425	KMOT	81,517	79,504	700
70034	KMOV	3,035,077	3,029,405	26,668
51488	KMPH–TV	1,725,397	1,697,871	14,946
73701	KMPX	6,678,829	6,674,706	58,757
44052	KMSB	1,321,614	1,039,442	9,150
68883	KMSP–TV	3,832,040	3,805,141	33,497
12525	KMSS–TV	1,068,120	1,066,388	9,387
43095	KMTP–TV	5,252,062	4,457,617	39,240
35189	KMTR	589,948	520,666	4,583
35190	KMTV–TV	1,346,549	1,344,796	11,838
77063	KMTW	761,521	761,516	6,704
35200	KMVT	184,647	176,351	1,552
32958	KMVU–DT	308,150	231,506	2,038
86534	KMYA–DT	200,764	200,719	1,767
51518	KMYS	2,273,888	2,267,913	19,964
54420	KMYT–TV	1,314,197	1,302,378	11,465
35822	KMYU	133,563	130,198	1,146
993	KNAT–TV	1,157,630	1,124,619	9,900
24749	KNAZ–TV	332,321	227,658	2,004
47906	KNBC	17,859,647	16,555,232	145,736
81464	KNBN	145,493	136,995	1,206
9754	KNCT	1,751,838	1,726,148	15,195
82611	KNDB	118,154	118,122	1,040
82615	KNDM	72,216	72,209	636
12395	KNDO	314,875	270,892	2,385
12427	KNDU	475,612	462,556	4,072
17683	KNEP	101,389	95,890	844
48003	KNHL	277,777	277,308	2,441
125710	KNIC–DT	2,398,296	2,383,294	20,980
59363	KNIN–TV	708,289	703,838	6,196
48525	KNLC	2,981,508	2,978,979	26,224
48521	KNLJ	655,000	642,705	5,658
84215	KNMD–TV	1,135,642	1,108,358	9,757
55528	KNME–TV	1,148,741	1,105,095	9,728
47707	KNMT	2,887,142	2,794,995	24,604
48975	KNOE–TV	733,097	729,703	6,424
49273	KNOP–TV	87,904	85,423	752
10228	KNPB	604,614	462,732	4,073
55362	KNRR	25,957	25,931	228
35277	KNSD	3,861,660	3,618,321	31,852
19191	KNSN–TV	611,981	459,485	4,045
23302	KNSO	1,824,786	1,803,796	15,879
35280	KNTV	8,525,818	8,027,505	70,666
144	KNVA	2,550,225	2,529,184	22,264
33745	KNVN	495,902	470,252	4,140
69692	KNVO	1,247,014	1,247,014	10,977
29557	KNWA–TV	822,906	804,682	7,084
59440	KNXV–TV	4,183,943	4,173,022	36,735
59014	KOAA–TV	1,608,528	1,203,731	10,596
50588	KOAB–TV	207,070	203,371	1,790
50590	KOAC–TV	1,957,282	1,543,401	13,587
58552	KOAM–TV	595,307	584,921	5,149
53928	KOAT–TV	1,132,372	1,105,116	9,728
35313	KOB	1,152,841	1,113,162	9,799
35321	KOBF	201,911	166,177	1,463

TABLE 7—FY 2022 FULL-SERVICE BROADCAST TELEVISION STATIONS BY CALL SIGN—Continued

Facility Id.	Call sign	Service area population	Terrain limited population	Terrain limited fee amount
8260	KOBI	562,463	519,063	4,569
62272	KOBR	211,709	211,551	1,862
50170	KOCB	1,629,783	1,629,152	14,341
4328	KOCE–TV	17,446,133	16,461,581	144,911
84225	KOCM	1,434,325	1,433,605	12,620
12508	KOCO–TV	1,716,569	1,708,085	15,036
83181	KOCW	83,807	83,789	738
18283	KODE–TV	740,156	731,512	6,440
66195	KOED–TV	1,497,297	1,459,833	12,851
50198	KOET	658,606	637,640	5,613
51189	KOFY–TV	5,252,062	4,457,617	39,240
34859	KOGG	190,829	161,310	1,420
166534	KOHD	201,310	197,662	1,740
35380	KOIN	3,028,482	2,881,460	25,365
35388	KOKH–TV	1,627,116	1,625,246	14,307
11910	KOKI–TV	1,366,220	1,352,227	11,904
48663	KOLD–TV	1,216,228	887,754	7,815
7890	KOLN	1,225,400	1,190,178	10,477
63331	KOLO–TV	959,178	826,985	7,280
28496	KOLR	1,076,144	1,038,613	9,143
21656	KOMO–TV	4,132,260	4,087,435	35,982
65583	KOMU–TV	551,658	542,544	4,776
35396	KONG	4,006,008	3,985,271	35,082
60675	KOOD	113,416	113,285	997
50589	KOPB–TV	3,059,231	2,875,815	25,316
2566	KOPX–TV	1,501,110	1,500,883	13,212
64877	KORO	560,983	560,983	4,938
6865	KOSA–TV	340,978	338,070	2,976
34347	KOTA–TV	174,876	152,861	1,346
8284	KOTI	298,175	97,132	855
35434	KOTV–DT	1,417,753	1,403,838	12,358
56550	KOVR	10,784,477	7,162,989	63,056
51101	KOZJ	429,982	427,991	3,768
51102	KOZK	839,841	834,308	7,344
3659	KOZL–TV	992,495	963,281	8,480
35455	KPAX–TV	206,895	193,201	1,701
67868	KPAZ–TV	4,190,080	4,176,323	36,764
6124	KPBS	3,584,237	3,463,189	30,486
50044	KPBT–TV	340,080	340,080	2,994
77452	KPCB–DT	30,861	30,835	271
35460	KPDX	2,970,703	2,848,423	25,075
12524	KPEJ–TV	368,212	368,208	3,241
41223	KPHO–TV	4,195,073	4,175,139	36,754
61551	KPIC	156,687	105,807	931
86205	KPIF	265,080	258,174	2,273
25452	KPIX–TV	8,226,463	7,360,625	64,796
58912	KPJK	7,884,411	6,955,179	61,226
166510	KPJR–TV	3,402,088	3,372,831	29,691
13994	KPLC	1,406,085	1,403,853	12,358
41964	KPLO–TV	55,827	52,765	464
35417	KPLR–TV	2,991,598	2,988,106	26,304
12144	KPMR	1,731,370	1,473,251	12,969
47973	KPNE–TV	92,675	89,021	784
35486	KPNX	4,180,982	4,176,442	36,765
77512	KPNZ	2,394,311	2,208,707	19,443
73998	KPOB–TV	144,525	143,656	1,265
26655	KPPX–TV	4,186,998	4,171,450	36,721
53117	KPRC–TV	6,099,422	6,099,076	53,690
48660	KPRY–TV	42,521	42,426	373
61071	KPSD–TV	19,886	18,799	165
53544	KPTB–DT	322,780	320,646	2,823
81445	KPTF–DT	84,512	84,512	744
77451	KPTH	660,556	655,373	5,769
51491	KPTM	1,414,998	1,414,014	12,448
33345	KPTS	832,000	827,866	7,288
50633	KPTV	2,998,460	2,847,263	25,064
82575	KPTW	80,374	80,012	704
1270	KPVI–DT	271,379	264,204	2,326
58835	KPXB–TV	6,062,458	6,062,238	53,366
68695	KPXC–TV	3,362,518	3,341,951	29,419
68834	KPXD–TV	6,555,157	6,553,373	57,689

TABLE 7—FY 2022 FULL-SERVICE BROADCAST TELEVISION STATIONS BY CALL SIGN—Continued

Facility Id.	Call sign	Service area population	Terrain limited population	Terrain limited fee amount
33337	KPXE–TV	2,437,178	2,436,024	21,444
5801	KPXG–TV	3,026,219	2,882,598	25,376
81507	KPXJ	1,138,632	1,135,626	9,997
61173	KPXL–TV	2,257,007	2,243,520	19,750
35907	KPXM–TV	3,507,312	3,506,503	30,868
58978	KPXN–TV	17,256,205	15,804,489	139,127
77483	KPXO–TV	953,329	913,341	8,040
21156	KPXR–TV	828,915	821,250	7,229
10242	KQCA	10,077,891	6,276,197	55,249
41430	KQCD–TV	35,623	33,415	294
18287	KQCK	3,220,160	3,162,711	27,841
78322	KQCW–DT	1,128,198	1,123,324	9,889
35525	KQDS–TV	304,935	301,439	2,654
35500	KQED	8,195,398	7,283,828	64,120
35663	KQEH	8,195,398	7,283,828	64,120
8214	KQET	2,981,040	2,076,157	18,276
5471	KQIN	596,371	596,277	5,249
17686	KQME	188,783	184,719	1,626
61063	KQSD–TV	32,526	31,328	276
8378	KQSL	196,316	139,439	1,227
20427	KQTV	1,494,987	1,401,160	12,334
78921	KQUP	697,016	551,824	4,858
306	KRBC–TV	229,395	229,277	2,018
166319	KRBK	983,888	966,187	8,505
22161	KRCA	17,540,791	16,957,292	149,275
57945	KRCB	8,783,441	8,503,802	74,859
41110	KRCG	684,989	662,418	5,831
8291	KRCR–TV	423,000	402,594	3,544
10192	KRCW–TV	2,966,912	2,842,523	25,023
49134	KRDK–TV	349,941	349,929	3,080
52579	KRDO–TV	2,622,603	2,272,383	20,004
70578	KREG–TV	149,306	95,141	838
34868	KREM	817,619	752,113	6,621
51493	KREN–TV	810,039	681,212	5,997
70596	KREX–TV	145,700	145,606	1,282
70579	KREY–TV	74,963	65,700	578
48589	KREZ–TV	148,079	105,121	925
43328	KRGV–TV	1,247,057	1,247,029	10,978
82698	KRII	133,840	132,912	1,170
29114	KRIN	949,313	923,735	8,132
25559	KRIS–TV	565,052	563,805	4,963
22204	KRIV	6,078,936	6,078,846	53,512
14040	KRMA–TV	3,722,512	3,564,949	31,382
14042	KRMJ	174,094	159,511	1,404
20476	KRMT	2,956,144	2,864,236	25,214
84224	KRMU	85,274	72,499	638
20373	KRMZ	36,293	33,620	296
47971	KRNE–TV	47,473	38,273	337
60307	KRNV–DT	955,490	792,543	6,977
65526	KRON–TV	8,573,167	8,028,256	70,673
53539	KRPV–DT	65,943	65,943	580
48575	KRQE	1,135,461	1,105,093	9,728
57431	KRSU–TV	1,000,289	998,310	8,788
82613	KRTN–TV	84,231	68,550	603
35567	KRTV	92,645	90,849	800
84157	KRWB–TV	111,538	110,979	977
35585	KRWF	85,596	85,596	754
55516	KRWG–TV	894,492	661,703	5,825
48360	KRXI–TV	725,391	548,865	4,832
307	KSAN–TV	135,063	135,051	1,189
11911	KSAS–TV	752,513	752,504	6,624
53118	KSAT–TV	2,539,658	2,502,246	22,027
35584	KSAX	365,209	365,209	3,215
35587	KSAZ–TV	4,203,126	4,178,448	36,783
38214	KSBI	1,577,231	1,575,865	13,872
19653	KSBW	5,083,461	4,429,165	38,990
19654	KSBY	535,029	495,562	4,362
82910	KSCC	517,740	517,740	4,558
10202	KSCE	1,015,148	1,010,581	8,896
35608	KSCI	17,446,133	16,461,581	144,911
72348	KSCW–DT	915,691	910,511	8,015

TABLE 7—FY 2022 FULL-SERVICE BROADCAST TELEVISION STATIONS BY CALL SIGN—Continued

Facility Id.	Call sign	Service area population	Terrain limited population	Terrain limited fee amount
46981	KSDK	2,986,776	2,979,047	26,225
35594	KSEE	1,761,193	1,746,282	15,373
48658	KSFY–TV	670,536	607,844	5,351
17680	KSGW–TV	62,178	57,629	507
59444	KSHB–TV	2,432,205	2,431,273	21,402
73706	KSHV–TV	943,947	942,978	8,301
29096	KSIN–TV	340,143	338,811	2,983
34846	KSIX–TV	74,884	74,884	659
35606	KSKN	731,818	643,590	5,666
70482	KSLA	1,017,556	1,016,667	8,950
6359	KSL–TV	2,390,742	2,206,920	19,428
71558	KSMN	320,813	320,808	2,824
33336	KSMO–TV	2,401,201	2,398,686	21,116
28510	KSMQ–TV	524,391	507,983	4,472
35611	KSMS–TV	1,589,263	882,948	7,773
21161	KSNB–TV	658,560	656,650	5,780
72359	KSNC	174,135	173,744	1,529
67766	KSNF	621,919	617,868	5,439
72361	KSNG	145,058	144,822	1,275
72362	KSNK	48,715	45,414	400
67335	KSNT	622,818	594,604	5,234
10179	KSNV	1,967,781	1,919,296	16,896
72358	KSNW	791,403	791,127	6,964
61956	KSPS–TV	819,101	769,852	6,777
52953	KSPX–TV	7,078,228	5,275,946	46,444
166546	KSQA	382,328	374,290	3,295
53313	KSRE	75,181	75,181	662
35843	KSTC–TV	3,843,788	3,835,674	33,765
63182	KSTF	51,317	51,122	450
28010	KSTP–TV	3,788,898	3,782,053	33,293
60534	KSTR–DT	6,632,577	6,629,296	58,358
64987	KSTS	8,363,473	7,264,852	63,952
22215	KSTU	2,384,996	2,201,716	19,382
23428	KSTW	4,265,956	4,186,266	36,852
5243	KSVI	175,390	173,667	1,529
58827	KSWB–TV	3,677,190	3,488,655	30,711
60683	KSWK	79,012	78,784	694
35645	KSWO–TV	483,132	458,057	4,032
61350	KSYS	519,209	443,204	3,902
59988	KTAB–TV	274,707	274,536	2,417
999	KTAJ–TV	2,343,843	2,343,227	20,627
35648	KTAL–TV	1,094,332	1,092,958	9,621
12930	KTAS	471,882	464,149	4,086
81458	KTAZ	4,182,503	4,160,481	36,625
35649	KTBC	3,242,215	2,956,614	26,027
67884	KTBN–TV	17,795,677	16,510,302	145,340
67999	KTBO–TV	1,585,283	1,583,664	13,941
35652	KTBS–TV	1,163,228	1,159,665	10,209
28324	KTBU	6,035,927	6,035,725	53,132
67950	KTBW–TV	4,202,104	4,108,031	36,163
35655	KTBY	348,080	346,562	3,051
68594	KTCA–TV	3,693,877	3,684,081	32,431
68597	KTCI–TV	3,606,606	3,597,183	31,666
35187	KTCW	103,341	89,207	785
36916	KTDO	1,015,336	1,010,771	8,898
2769	KTEJ	419,750	417,368	3,674
83707	KTEL–TV	52,878	52,875	465
35666	KTEN	602,788	599,778	5,280
24514	KTFD–TV	3,210,669	3,172,543	27,928
35512	KTFF–DT	2,225,169	2,203,398	19,397
20871	KTFK–DT	6,969,307	5,211,719	45,879
68753	KTFN	1,017,335	1,013,157	8,919
35084	KTFQ–TV	1,151,433	1,117,061	9,833
29232	KTGM	159,358	159,091	1,400
2787	KTHV	1,275,053	1,246,348	10,972
29100	KTIN	281,096	279,385	2,459
66170	KTIV	751,089	746,274	6,569
49397	KTKA–TV	759,369	746,370	6,570
35670	KTLA	18,156,910	16,870,262	148,509
62354	KTLM	1,044,526	1,044,509	9,195
49153	KTLN–TV	5,381,955	4,740,894	41,734

TABLE 7—FY 2022 FULL-SERVICE BROADCAST TELEVISION STATIONS BY CALL SIGN—Continued

Facility Id.	Call sign	Service area population	Terrain limited population	Terrain limited fee amount
64984	KTMD	6,095,741	6,095,606	53,660
14675	KTMF	187,251	168,526	1,484
10177	KTMW	2,261,671	2,144,791	18,881
21533	KTNC–TV	8,270,858	7,381,656	64,981
47996	KTNE–TV	100,341	95,324	839
60519	KTNL–TV	8,642	8,642	76
74100	KTNV–TV	2,094,506	1,936,752	17,049
71023	KTNW	450,926	432,398	3,806
8651	KTOO–TV	31,269	31,176	274
7078	KTPX–TV	1,066,196	1,063,754	9,364
68541	KTRE	441,879	421,406	3,710
35675	KTRK–TV	6,114,259	6,112,870	53,812
28230	KTRV–TV	714,833	707,557	6,229
69170	KTSC	3,124,536	2,949,795	25,967
61066	KTSD–TV	83,645	82,828	729
37511	KTSF	7,959,349	7,129,638	62,762
67760	KTSM–TV	1,015,348	1,011,264	8,902
35678	KTTC	815,213	731,919	6,443
28501	KTTM	76,133	73,664	648
11908	KTTU	1,324,801	1,060,613	9,337
22208	KTTV	17,380,551	16,693,085	146,949
28521	KTTW	329,633	326,405	2,873
65355	KTTZ–TV	380,240	380,225	3,347
35685	KTUL	1,416,959	1,388,183	12,220
10173	KTUU–TV	380,240	379,047	3,337
77480	KTUZ–TV	1,668,531	1,666,026	14,666
49632	KTVA	342,517	342,300	3,013
34858	KTVB	714,865	707,882	6,231
31437	KTVC	137,239	100,204	882
68581	KTVD	3,800,970	3,547,607	31,230
35692	KTVE	641,139	640,201	5,636
49621	KTVF	98,068	97,929	862
5290	KTVH–DT	228,832	184,264	1,622
35693	KTVI	2,995,764	2,991,513	26,334
40993	KTVK	4,184,825	4,173,028	36,735
22570	KTVL	419,849	369,469	3,252
18066	KTVM–TV	260,105	217,694	1,916
59139	KTVN	955,490	800,420	7,046
21251	KTVO	227,128	226,616	1,995
35694	KTVQ	179,797	173,271	1,525
50592	KTVR	147,808	54,480	480
23422	KTVT	6,912,366	6,908,715	60,817
35703	KTVU	8,297,634	7,406,751	65,202
35705	KTVW–DT	4,174,310	4,160,877	36,628
68889	KTVX	2,389,392	2,200,520	19,371
55907	KTVZ	201,828	198,558	1,748
18286	KTWO–TV	80,426	79,905	703
70938	KTWU	1,703,798	1,562,305	13,753
51517	KTXA	6,915,461	6,911,822	60,845
42359	KTXD–TV	6,706,651	6,704,781	59,022
51569	KTXH	6,092,710	6,092,525	53,632
10205	KTXL	8,306,449	5,896,320	51,905
308	KTXS–TV	247,603	246,760	2,172
69315	KUAC–TV	98,717	98,189	864
51233	KUAM–TV	159,358	159,358	1,403
2722	KUAS–TV	994,802	977,391	8,604
2731	KUAT–TV	1,485,024	1,253,342	11,033
60520	KUBD	14,817	13,363	118
70492	KUBE–TV	6,090,970	6,090,817	53,617
1136	KUCW	2,388,889	2,199,787	19,365
69396	KUED	2,388,995	2,203,093	19,394
69582	KUEN	2,364,481	2,184,483	19,230
82576	KUES	30,925	25,978	229
82585	KUEW	132,168	120,411	1,060
66611	KUFM–TV	187,680	166,697	1,467
169028	KUGF–TV	86,622	85,986	757
68717	KUHM–TV	154,836	145,241	1,279
69269	KUHT	6,080,222	6,078,866	53,512
62382	KUID–TV	432,855	284,023	2,500
169027	KUKL–TV	124,505	115,844	1,020
35724	KULR–TV	177,242	170,142	1,498

TABLE 7—FY 2022 FULL-SERVICE BROADCAST TELEVISION STATIONS BY CALL SIGN—Continued

Facility Id.	Call sign	Service area population	Terrain limited population	Terrain limited fee amount
41429	KUMV–TV	41,607	41,224	363
81447	KUNP	130,559	43,472	383
4624	KUNS–TV	4,027,849	4,015,626	35,350
86532	KUOK	28,974	28,945	255
66589	KUON–TV	1,375,257	1,360,005	11,972
86263	KUPB	318,914	318,914	2,807
65535	KUPK	149,642	148,180	1,304
27431	KUPT	87,602	87,602	771
89714	KUPU	956,178	948,005	8,345
57884	KUPX–TV	2,374,672	2,191,229	19,289
23074	KUSA	3,802,407	3,560,546	31,343
61072	KUSD–TV	460,480	460,277	4,052
10238	KUSI–TV	3,572,818	3,435,670	30,244
43567	KUSM–TV	122,678	109,830	967
69694	KUTF	1,210,774	1,031,870	9,084
81451	KUTH–DT	2,219,788	2,027,174	17,845
68886	KUTP	4,191,015	4,176,014	36,761
35823	KUTV	2,388,625	2,199,731	19,364
63927	KUVE–DT	1,294,971	964,396	8,490
7700	KUVI–DT	1,204,490	1,009,943	8,891
35841	KUVN–DT	6,680,126	6,678,157	58,788
58609	KUVS–DT	4,043,413	4,005,657	35,262
49766	KVAL–TV	1,016,673	866,173	7,625
32621	KVAW	76,153	76,153	670
58795	KVCR–DT	18,215,524	17,467,140	153,763
35846	KVCT	288,221	287,446	2,530
10195	KVCW	1,967,550	1,918,809	16,891
64969	KVDA	2,566,563	2,548,720	22,436
19783	KVEA	17,538,249	16,335,335	143,800
12523	KVEO–TV	1,244,504	1,244,504	10,955
2495	KVEW	476,720	464,347	4,088
35852	KVHP	747,917	747,837	6,583
49832	KVIA–TV	1,015,350	1,011,266	8,902
35855	KVIE	10,759,440	7,467,369	65,735
40450	KVIH–TV	91,912	91,564	806
40446	KVII–TV	379,042	378,218	3,329
61961	KVLY–TV	350,732	350,449	3,085
16729	KVMD	15,274,297	14,512,400	127,753
83825	KVME–TV	26,711	22,802	201
25735	KVOA	1,317,956	1,030,404	9,071
35862	KVOS–TV	2,202,674	2,131,652	18,765
69733	KVPT	1,744,349	1,719,318	15,135
55372	KVRR	356,645	356,645	3,140
166331	KVSN–DT	2,706,244	2,283,409	20,101
608	KVTH–DT	303,755	299,230	2,634
2784	KVTJ–DT	1,466,426	1,465,802	12,903
607	KVTN–DT	936,328	925,884	8,151
35867	KVUE	2,661,290	2,611,314	22,987
78910	KVUI	257,964	251,872	2,217
35870	KVVU–TV	2,045,255	1,935,583	17,039
36170	KVYE	396,495	392,498	3,455
35095	KWBA–TV	1,129,524	1,073,029	9,446
78314	KWBM	657,822	639,560	5,630
27425	KWBN	953,207	840,455	7,399
76268	KWBQ	1,149,598	1,107,211	9,747
66413	KWCH–DT	883,647	881,674	7,761
71549	KWCM–TV	252,284	244,033	2,148
35419	KWDK	4,194,152	4,117,852	36,249
42007	KWES–TV	424,862	423,544	3,728
50194	KWET	127,976	112,750	993
35881	KWEX–DT	2,376,463	2,370,469	20,867
35883	KWGN–TV	3,706,455	3,513,537	30,930
37099	KWHB	979,393	978,719	8,616
36846	KWHE	952,966	834,341	7,345
26231	KWHY–TV	17,736,497	17,695,306	155,772
35096	KWKB	1,121,676	1,111,629	9,786
162115	KWKS	39,708	39,323	346
12522	KWKT–TV	1,299,675	1,298,478	11,431
21162	KWNB–TV	91,093	89,332	786
67347	KWOG	512,412	505,049	4,446
56852	KWPX–TV	4,220,008	4,148,577	36,520

TABLE 7—FY 2022 FULL-SERVICE BROADCAST TELEVISION STATIONS BY CALL SIGN—Continued

Facility Id.	Call sign	Service area population	Terrain limited population	Terrain limited fee amount
6885	KWQC–TV	1,063,507	1,054,618	9,284
29121	KWSD	280,675	280,672	2,471
53318	KWSE	54,471	53,400	470
71024	KWSU–TV	725,554	468,295	4,122
25382	KWTV–DT	1,628,106	1,627,198	14,324
35903	KWTX–TV	2,071,023	1,972,365	17,363
593	KWWL	1,089,498	1,078,458	9,494
84410	KWWT	293,291	293,291	2,582
14674	KWYB	86,495	69,598	613
10032	KWYP–DT	128,874	126,992	1,118
35920	KXAN–TV	2,678,666	2,624,648	23,105
49330	KXAS–TV	6,774,295	6,771,827	59,612
24287	KXGN–TV	14,217	13,883	122
35954	KXII	2,323,974	2,264,951	19,938
55083	KXLA	17,929,100	16,794,896	147,845
35959	KXLF–TV	258,100	217,808	1,917
53847	KXLN–DT	6,085,891	6,085,712	53,573
35906	KXLT–TV	348,025	347,296	3,057
61978	KXLY–TV	772,116	740,960	6,523
55684	KXMA–TV	32,005	31,909	281
55686	KXMB–TV	142,755	138,506	1,219
55685	KXMC–TV	97,569	89,483	788
55683	KXMD–TV	37,962	37,917	334
47995	KXNE–TV	305,839	304,682	2,682
81593	KXNW	602,168	597,747	5,262
35991	KXRM–TV	1,843,363	1,500,689	13,211
1255	KXTF	140,746	140,312	1,235
25048	KXTV	10,759,864	7,477,140	65,821
35994	KXTX–TV	6,721,578	6,718,616	59,144
62293	KXVA	185,478	185,276	1,631
23277	KXVO	1,404,703	1,403,380	12,354
9781	KXXV	1,771,620	1,748,287	15,390
31870	KYAZ	6,038,257	6,038,071	53,153
29086	KYIN	581,748	574,691	5,059
60384	KYLE–TV	323,330	323,225	2,845
33639	KYMA–DT	396,278	391,619	3,447
47974	KYNE–TV	980,094	979,887	8,626
53820	KYOU–TV	651,334	640,935	5,642
36003	KYTV	1,095,904	1,083,524	9,538
55644	KYTX	927,327	925,550	8,148
13815	KYUR	379,943	379,027	3,337
5237	KYUS–TV	12,496	12,356	109
33752	KYVE	301,951	259,559	2,285
55762	KYVV–TV	67,201	67,201	592
25453	KYW–TV	11,212,189	11,008,413	96,907
69531	KZJL	6,037,458	6,037,272	53,146
69571	KZJO	4,147,016	4,097,776	36,073
61062	KZSD–TV	41,207	35,825	315
33079	KZTV	567,635	564,464	4,969
57292	WAAY–TV	1,498,006	1,428,197	12,572
1328	WABC–TV	20,948,273	20,560,001	180,990
4190	WABE–TV	5,308,575	5,291,523	46,581
43203	WABG–TV	393,020	392,348	3,454
17005	WABI–TV	530,773	510,729	4,496
16820	WABM	1,772,367	1,742,240	15,337
23917	WABW–TV	1,097,560	1,096,376	9,651
19199	WACH	1,403,222	1,400,385	12,328
189358	WACP	9,415,263	9,301,049	81,877
23930	WACS–TV	786,536	783,207	6,895
60018	WACX	4,292,829	4,288,149	37,749
361	WACY–TV	946,580	946,071	8,328
455	WADL	4,610,065	4,606,521	40,551
589	WAFB	1,857,882	1,857,418	16,351
591	WAFF	1,527,517	1,456,436	12,821
70689	WAGA–TV	6,000,355	5,923,191	52,142
48305	WAGM–TV	64,721	63,331	558
37809	WAGV	1,313,257	1,159,076	10,203
706	WAIQ	611,733	609,794	5,368
701	WAKA	799,637	793,645	6,986
4143	WALA–TV	1,320,419	1,318,127	11,603
70713	WALB	773,899	772,467	6,800

TABLE 7—FY 2022 FULL-SERVICE BROADCAST TELEVISION STATIONS BY CALL SIGN—Continued

Facility Id.	Call sign	Service area population	Terrain limited population	Terrain limited fee amount
60536	WAMI–DT	5,449,193	5,449,193	47,969
70852	WAND	1,388,118	1,386,074	12,202
39270	WANE–TV	1,146,442	1,146,442	10,092
52280	WAOE	2,963,253	2,907,224	25,592
64546	WAOW	636,957	629,068	5,538
52073	WAPA–TV[27]	3,764,742	2,794,738	24,602
49712	WAPT	793,621	791,620	6,969
67792	WAQP	2,135,670	2,131,399	18,763
13206	WATC–DT	5,732,204	5,705,819	50,228
71082	WATE–TV	1,874,433	1,638,059	14,420
22819	WATL	5,882,837	5,819,099	51,226
20287	WATM–TV	893,989	749,183	6,595
11907	WATN–TV	1,787,595	1,784,560	15,709
13989	WAVE	1,891,797	1,880,563	16,555
71127	WAVY–TV	2,080,708	2,080,691	18,316
54938	WAWD	579,079	579,023	5,097
65247	WAWV–TV	705,790	700,361	6,165
12793	WAXN–TV	2,677,951	2,669,224	23,497
65696	WBAL–TV	9,743,335	9,344,875	82,263
74417	WBAY–TV	1,225,928	1,225,335	10,787
71085	WBBH–TV	2,017,267	2,017,267	17,758
65204	WBBJ–TV	662,148	658,839	5,800
9617	WBBM–TV	9,914,233	9,907,806	87,218
9088	WBBZ–TV	1,269,256	1,260,686	11,098
70138	WBDT	3,831,757	3,819,550	33,623
51349	WBEC–TV	5,421,355	5,421,355	47,724
10758	WBFF	8,523,983	8,381,042	73,778
12497	WBFS–TV	5,349,613	5,349,613	47,093
6568	WBGU–TV	1,343,816	1,343,816	11,830
81594	WBIF	309,707	309,707	2,726
84802	WBIH	718,439	706,994	6,224
717	WBIQ	1,563,080	1,532,266	13,489
46984	WBIR–TV	1,978,347	1,701,857	14,981
67048	WBKB–TV	136,823	130,625	1,150
34167	WBKI	2,104,090	2,085,393	18,358
4692	WBKO	963,413	862,651	7,594
76001	WBKP	55,655	55,305	487
68427	WBMM	562,284	562,123	4,948
73692	WBNA	1,699,683	1,666,248	14,668
23337	WBNG–TV	1,435,634	1,051,932	9,260
71217	WBNS–TV	2,847,721	2,784,795	24,515
72958	WBNX–TV	3,639,256	3,630,531	31,960
71218	WBOC–TV	813,888	813,888	7,165
71220	WBOY–TV	711,302	621,367	5,470
60850	WBPH–TV	10,613,847	9,474,797	83,407
7692	WBPX–TV	6,833,712	6,761,949	59,525
5981	WBRA–TV	1,726,408	1,677,204	14,764
71221	WBRC	1,884,007	1,849,135	16,278
71225	WBRE–TV	2,879,196	2,244,735	19,760
38616	WBRZ–TV	2,223,336	2,222,309	19,563
82627	WBSF	1,836,543	1,832,446	16,131
30826	WBTV	4,433,795	4,296,893	37,826
66407	WBTW	1,975,457	1,959,172	17,247
16363	WBUI	981,884	981,868	8,643
59281	WBUP	126,472	112,603	991
60830	WBUY–TV	1,569,254	1,567,815	13,801
72971	WBXX–TV	2,142,759	1,984,544	17,470
25456	WBZ–TV	7,960,556	7,730,847	68,055
63153	WCAU	11,269,831	11,098,540	97,700
363	WCAV	1,032,270	874,886	7,702
46728	WCAX–TV	784,748	665,685	5,860
39659	WCBB	964,079	910,222	8,013
10587	WCBD–TV	1,149,489	1,149,489	10,119
12477	WCBI–TV	680,511	678,424	5,972
9610	WCBS–TV	22,087,789	21,511,236	189,363
49157	WCCB	3,642,232	3,574,928	31,470
9629	WCCO–TV	3,837,442	3,829,714	33,713
14050	WCCT–TV	5,818,471	5,307,612	46,723
69544	WCCU	694,550	693,317	6,103
3001	WCCV–TV	3,391,703	2,062,994	18,161
23937	WCES–TV	1,098,868	1,097,706	9,663

TABLE 7—FY 2022 FULL-SERVICE BROADCAST TELEVISION STATIONS BY CALL SIGN—Continued

Facility Id.	Call sign	Service area population	Terrain limited population	Terrain limited fee amount
65666	WCET	3,123,290	3,110,519	27,382
46755	WCFE–TV	459,417	419,756	3,695
71280	WCHS–TV	1,352,824	1,274,766	11,222
42124	WCIA	834,084	833,547	7,338
711	WCIQ	3,186,320	3,016,907	26,558
71428	WCIU–TV	10,052,136	10,049,244	88,463
9015	WCIV	1,152,800	1,152,800	10,148
42116	WCIX	554,002	549,911	4,841
16993	WCJB–TV	977,492	977,492	8,605
11125	WCLF	4,097,389	4,096,624	36,063
68007	WCLJ–TV	2,305,723	2,303,534	20,278
50781	WCMH–TV	2,756,260	2,712,989	23,882
9917	WCML	233,439	224,255	1,974
9908	WCMU–TV	707,702	699,551	6,158
9922	WCMV	425,499	411,288	3,621
9913	WCMW	106,975	104,859	923
32326	WCNC–TV	3,883,049	3,809,706	33,537
53734	WCNY–TV	1,342,821	1,279,429	11,263
73642	WCOV–TV	889,102	884,417	7,786
40618	WCPB	560,426	560,426	4,933
59438	WCPO–TV	3,330,885	3,313,654	29,170
10981	WCPX–TV	9,753,235	9,751,916	85,846
71297	WCSC–TV	1,028,018	1,028,018	9,050
39664	WCSH	1,755,325	1,548,824	13,634
69479	WCTE	612,760	541,314	4,765
18334	WCTI–TV	1,688,065	1,685,638	14,839
31590	WCTV	1,065,524	1,065,464	9,379
33081	WCTX	7,844,936	7,332,431	64,547
65684	WCVB–TV	7,780,868	7,618,496	67,066
9987	WCVE–TV	1,721,004	1,712,249	15,073
83304	WCVI–TV	50,601	50,495	445
34204	WCVN–TV	2,129,816	2,120,349	18,665
9989	WCVW	1,505,484	1,505,330	13,251
73042	WCWF	1,077,314	1,077,194	9,483
35385	WCWG	3,630,551	3,299,114	29,042
29712	WCWJ	1,661,270	1,661,132	14,623
73264	WCWN	1,909,223	1,621,751	14,276
2455	WCYB–TV	2,363,002	2,057,404	18,111
11291	WDAF–TV	2,539,581	2,537,411	22,337
21250	WDAM–TV	512,594	500,343	4,405
22129	WDAY–TV	339,239	338,856	2,983
22124	WDAZ–TV	151,720	151,659	1,335
71325	WDBB	1,792,728	1,762,643	15,517
71326	WDBD	940,665	939,489	8,270
71329	WDBJ	1,626,017	1,435,762	12,639
51567	WDCA	8,101,358	8,049,329	70,858
16530	WDCQ–TV	1,269,199	1,269,199	11,173
30576	WDCW	8,155,998	8,114,847	71,435
54385	WDEF–TV	1,730,762	1,530,403	13,472
32851	WDFX–TV	271,499	270,942	2,385
43846	WDHN	452,377	451,978	3,979
71338	WDIO–DT	341,506	327,469	2,883
714	WDIQ	663,062	620,124	5,459
53114	WDIV–TV	5,450,318	5,450,174	47,978
71427	WDJT–TV	3,267,652	3,256,507	28,667
39561	WDKA	658,699	658,277	5,795
64017	WDKY–TV	1,204,817	1,173,579	10,331
67893	WDLI–TV	4,147,298	4,114,920	36,224
72335	WDPB	596,888	596,888	5,254
83740	WDPM–DT	1,365,977	1,364,744	12,014
1283	WDPN–TV	11,594,463	11,467,616	100,949
6476	WDPX–TV	6,833,712	6,761,949	59,525
28476	WDRB	2,054,813	2,037,086	17,932
12171	WDSC–TV	3,389,559	3,389,559	29,838
17726	WDSE	330,994	316,643	2,787
71353	WDSI–TV	1,100,302	1,042,191	9,174
71357	WDSU	1,649,083	1,649,083	14,517
7908	WDTI	2,092,242	2,091,941	18,415
65690	WDTN	3,831,757	3,819,550	33,623
70592	WDTV	962,532	850,394	7,486
25045	WDVM–TV	3,074,837	2,646,508	23,297

TABLE 7—FY 2022 FULL-SERVICE BROADCAST TELEVISION STATIONS BY CALL SIGN—Continued

Facility Id.	Call sign	Service area population	Terrain limited population	Terrain limited fee amount
4110	WDWL	2,638,361	1,977,410	17,407
49421	WEAO	3,960,217	3,945,408	34,731
71363	WEAR–TV	1,520,973	1,520,386	13,384
7893	WEAU	1,006,393	971,050	8,548
61003	WEBA–TV	641,354	632,282	5,566
19561	WECN	2,886,669	2,157,288	18,991
48666	WECT	1,156,807	1,156,807	10,183
13602	WEDH	5,328,800	4,724,167	41,587
13607	WEDN	3,451,170	2,643,344	23,269
69338	WEDQ	5,379,887	5,365,612	47,233
21808	WEDU	5,379,887	5,365,612	47,233
13594	WEDW	5,996,408	5,544,708	48,810
13595	WEDY	5,328,800	4,724,167	41,587
24801	WEEK–TV	752,596	752,539	6,625
6744	WEFS	3,380,743	3,380,743	29,761
24215	WEHT	857,558	844,070	7,430
721	WEIQ	1,055,632	1,055,193	9,289
18301	WEIU–TV	458,480	458,416	4,035
69271	WEKW–TV	1,263,049	773,108	6,806
60825	WELF–TV	1,477,691	1,387,044	12,210
26602	WELU	2,248,146	1,678,682	14,777
40761	WEMT	1,726,085	1,186,706	10,447
69237	WENH–TV	4,500,498	4,328,222	38,101
71508	WENY–TV	656,240	517,754	4,558
83946	WEPH	604,105	602,833	5,307
81508	WEPX–TV	950,012	950,012	8,363
25738	WESH	4,063,973	4,053,252	35,681
65670	WETA–TV	8,315,499	8,258,807	72,702
69944	WETK	670,087	558,842	4,919
60653	WETM–TV	870,206	770,731	6,785
18252	WETP–TV	2,167,383	1,888,574	16,625
2709	WEUX	380,569	373,680	3,290
72041	WEVV–TV	752,417	751,094	6,612
59441	WEWS–TV	4,112,984	4,078,299	35,901
72052	WEYI–TV	3,715,686	3,652,991	32,157
72054	WFAA	6,917,502	6,907,616	60,808
81669	WFBD	817,914	817,389	7,195
69532	WFDC–DT	8,155,998	8,114,847	71,435
10132	WFFF–TV	633,649	552,182	4,861
25040	WFFT–TV	1,095,429	1,095,411	9,643
11123	WFGC	3,018,351	3,018,351	26,571
6554	WFGX	1,493,866	1,493,319	13,146
13991	WFIE	743,079	740,909	6,522
715	WFIQ	546,563	544,258	4,791
64592	WFLA–TV	5,583,544	5,576,649	49,091
22211	WFLD	9,957,301	9,954,828	87,632
72060	WFLI–TV	1,294,209	1,189,897	10,475
39736	WFLX	5,740,086	5,740,086	50,530
72062	WFMJ–TV	4,328,477	3,822,691	33,651
72064	WFMY–TV	4,772,783	4,746,167	41,781
39884	WFMZ–TV	10,613,847	9,474,797	83,407
83943	WFNA	1,391,519	1,390,447	12,240
47902	WFOR–TV	5,398,266	5,398,266	47,521
11909	WFOX–TV	1,603,324	1,603,324	14,114
40626	WFPT	5,829,153	5,442,279	47,908
21245	WFPX–TV	2,637,949	2,634,141	23,188
25396	WFQX–TV	537,340	534,314	4,704
9635	WFRV–TV	1,263,353	1,256,376	11,060
53115	WFSB	4,752,788	4,370,519	38,474
6093	WFSG	364,961	364,796	3,211
21801	WFSU–TV	576,105	576,093	5,071
11913	WFTC	3,787,177	3,770,207	33,189
64588	WFTS–TV	5,236,379	5,236,287	46,095
16788	WFTT–TV	4,523,828	4,521,879	39,806
72076	WFTV	3,882,888	3,882,888	34,181
70649	WFTX–TV	1,758,172	1,758,172	15,477
60553	WFTY–DT	5,678,755	5,560,460	48,949
25395	WFUP	234,863	234,436	2,064
60555	WFUT–DT	20,362,721	19,974,644	175,837
22108	WFWA	1,035,114	1,034,862	9,110
9054	WFXB	1,393,865	1,393,510	12,267

TABLE 7—FY 2022 FULL-SERVICE BROADCAST TELEVISION STATIONS BY CALL SIGN—Continued

Facility Id.	Call sign	Service area population	Terrain limited population	Terrain limited fee amount
3228	WFXG	1,070,032	1,057,760	9,311
70815	WFXL	793,637	785,106	6,911
19707	WFXP	583,315	562,500	4,952
24813	WFXR	1,426,061	1,286,450	11,325
6463	WFXT	7,494,070	7,400,830	65,150
22245	WFXU	218,273	218,273	1,921
43424	WFXV	702,682	612,494	5,392
25236	WFXW	274,078	270,967	2,385
41397	WFYI	2,389,627	2,388,970	21,030
53930	WGAL	6,287,688	5,610,833	49,392
2708	WGBA–TV	1,170,375	1,170,127	10,301
24314	WGBC	249,415	249,235	2,194
72099	WGBH–TV	7,711,842	7,601,732	66,918
12498	WGBO–DT	9,828,737	9,826,530	86,503
11113	WGBP–TV	1,820,589	1,812,232	15,953
72098	WGBX–TV	7,803,280	7,636,641	67,225
72096	WGBY–TV	4,470,009	3,739,675	32,920
72120	WGCL–TV	6,027,276	5,961,471	52,479
62388	WGCU	1,510,671	1,510,671	13,298
54275	WGEM–TV	361,598	356,682	3,140
27387	WGEN–TV	43,037	43,037	379
7727	WGFL	877,163	877,163	7,722
25682	WGGB–TV	3,443,386	3,053,436	26,879
11027	WGGN–TV	4,002,841	3,981,382	35,048
9064	WGGS–TV	2,759,326	2,705,067	23,813
72106	WGHP	4,174,964	4,123,106	36,296
710	WGIQ	363,849	363,806	3,203
12520	WGMB–TV	1,742,708	1,742,659	15,341
25683	WGME–TV	1,495,724	1,325,465	11,668
24618	WGNM	742,458	741,502	6,527
72119	WGNO	1,641,765	1,641,765	14,452
9762	WGNT	2,128,079	2,127,891	18,732
72115	WGN–TV	9,942,959	9,941,552	87,515
40619	WGPT	578,294	344,300	3,031
65074	WGPX–TV	2,765,350	2,754,743	24,250
64547	WGRZ	1,878,725	1,812,309	15,954
63329	WGTA	1,061,654	1,030,538	9,072
66285	WGTE–TV	2,210,496	2,208,927	19,445
59279	WGTQ	95,618	92,019	810
59280	WGTU	358,543	353,477	3,112
23948	WGTV	5,989,342	5,917,966	52,096
7623	WGTW–TV	807,797	807,797	7,111
24783	WGVK	2,439,225	2,437,526	21,458
24784	WGVU–TV	1,825,744	1,784,264	15,707
21536	WGWG	986,963	986,963	8,688
56642	WGWW	1,677,166	1,647,976	14,507
58262	WGXA	779,955	779,087	6,858
73371	WHAM–TV	1,381,564	1,334,653	11,749
32327	WHAS–TV	1,955,983	1,925,901	16,954
6096	WHA–TV	1,635,777	1,628,950	14,340
13950	WHBF–TV	1,712,339	1,704,072	15,001
12521	WHBQ–TV	1,736,335	1,708,345	15,039
10894	WHBR	1,302,764	1,302,041	11,462
65128	WHDF	1,553,469	1,502,852	13,230
72145	WHDH	7,441,208	7,343,735	64,647
83929	WHDT	5,768,239	5,768,239	50,778
70041	WHEC–TV	1,322,243	1,279,606	11,264
67971	WHFT–TV	5,417,409	5,417,409	47,689
41458	WHIO–TV	3,877,520	3,868,597	34,055
713	WHIQ	1,278,174	1,225,940	10,792
61216	WHIZ–TV	911,245	840,696	7,401
65919	WHKY–TV	3,358,493	3,294,261	28,999
18780	WHLA–TV	554,446	515,561	4,538
48668	WHLT	484,432	483,532	4,257
24582	WHLV–TV	3,906,201	3,906,201	34,386
37102	WHMB–TV	2,959,585	2,889,145	25,433
61004	WHMC	774,921	774,921	6,822
36117	WHME–TV	1,455,358	1,455,110	12,809
37106	WHNO	1,499,653	1,499,653	13,201
72300	WHNS	2,549,610	2,270,868	19,990
48693	WHNT–TV	1,569,885	1,487,578	13,095

TABLE 7—FY 2022 FULL-SERVICE BROADCAST TELEVISION STATIONS BY CALL SIGN—Continued

Facility Id.	Call sign	Service area population	Terrain limited population	Terrain limited fee amount
66221	WHO–DT	1,120,480	1,099,818	9,682
6866	WHOI	736,125	736,047	6,479
72313	WHP–TV	4,030,693	3,538,096	31,146
51980	WHPX–TV	5,579,464	5,114,336	45,021
73036	WHRM–TV	535,778	532,820	4,690
25932	WHRO–TV	2,169,238	2,169,237	19,096
68058	WHSG–TV	5,870,314	5,808,605	51,133
4688	WHSV–TV	845,013	711,912	6,267
9990	WHTJ	807,960	690,381	6,077
72326	WHTM–TV	2,829,585	2,367,000	20,837
11117	WHTN	1,914,755	1,905,733	16,776
27772	WHUT–TV	7,649,763	7,617,337	67,055
18793	WHWC–TV	1,123,941	1,091,281	9,607
72338	WHYY–TV	10,448,829	10,049,700	88,468
5360	WIAT	1,837,072	1,802,810	15,870
63160	WIBW–TV	1,234,347	1,181,009	10,396
25684	WICD	1,238,332	1,237,046	10,890
25686	WICS	1,149,358	1,147,264	10,099
24970	WICU–TV	740,115	683,435	6,016
62210	WICZ–TV	1,249,974	965,416	8,499
18410	WIDP	2,559,306	1,899,768	16,724
26025	WIFS	1,583,693	1,578,870	13,899
720	WIIQ	353,241	347,685	3,061
68939	WILL–TV	1,178,545	1,158,147	10,195
6863	WILX–TV	3,378,644	3,218,221	28,330
22093	WINK–TV	1,851,105	1,851,105	16,295
67787	WINM	1,001,485	971,031	8,548
41314	WINP–TV	2,935,057	2,883,944	25,387
3646	WIPB	1,965,353	1,965,174	17,299
48408	WIPL	850,656	799,165	7,035
53863	WIPM–TV [1]	2,196,157	1,554,017	2,543
53859	WIPR–TV [1]	3,596,802	2,811,148	24,747
10253	WIPX–TV	2,305,723	2,303,534	20,278
39887	WIRS [12]	1,091,825	757,978	5,281
71336	WIRT–DT	127,001	126,300	1,112
13990	WIS	2,644,715	2,600,887	22,896
65143	WISC–TV	1,734,112	1,697,537	14,943
13960	WISE–TV	1,070,155	1,070,155	9,421
39269	WISH–TV	2,912,963	2,855,253	25,135
65680	WISN–TV	3,003,636	2,997,695	26,389
73083	WITF–TV	2,412,561	2,191,501	19,292
73107	WITI	3,111,641	3,102,097	27,308
594	WITN–TV	1,861,458	1,836,905	16,170
61005	WITV	871,783	871,783	7,674
7780	WIVB–TV	1,900,503	1,820,106	16,022
11260	WIVT	855,138	613,934	5,404
60571	WIWN	3,338,845	3,323,941	29,261
62207	WIYC	639,641	637,499	5,612
73120	WJAC–TV	2,219,529	1,897,986	16,708
10259	WJAL	8,750,706	8,446,074	74,351
50780	WJAR	7,108,180	6,976,099	61,411
35576	WJAX–TV	1,630,782	1,630,782	14,356
27140	WJBF	1,601,088	1,588,444	13,983
73123	WJBK	5,748,623	5,711,224	50,276
37174	WJCL	938,086	938,086	8,258
73130	WJCT	1,618,817	1,617,292	14,237
29719	WJEB–TV	1,607,603	1,607,603	14,152
65749	WJET–TV	747,431	717,721	6,318
7651	WJFB	2,310,517	2,302,217	20,266
49699	WJFW–TV	277,530	268,295	2,362
73136	WJHG–TV	864,121	859,823	7,569
57826	WJHL–TV	2,034,663	1,462,129	12,871
68519	WJKT	655,780	655,373	5,769
1051	WJLA–TV	8,750,706	8,447,643	74,365
86537	WJLP	21,384,863	21,119,366	185,914
9630	WJMN–TV	160,991	154,424	1,359
61008	WJPM–TV	623,939	623,787	5,491
58340	WJPX [6 10 12]	3,254,481	2,500,195	22,009
21735	WJRT–TV	2,788,684	2,543,446	22,390
23918	WJSP–TV	4,225,860	4,188,428	36,871
41210	WJTC	1,381,529	1,379,283	12,142

TABLE 7—FY 2022 FULL-SERVICE BROADCAST TELEVISION STATIONS BY CALL SIGN—Continued

Facility Id.	Call sign	Service area population	Terrain limited population	Terrain limited fee amount
48667	WJTV	987,206	980,717	8,633
73150	WJW	3,977,148	3,905,325	34,379
61007	WJWJ–TV	1,034,555	1,034,555	9,107
58342	WJWN–TV[6]	2,063,156	1,461,497	5,281
53116	WJXT	1,622,616	1,622,616	14,284
11893	WJXX	1,618,191	1,617,272	14,237
32334	WJYS	9,667,341	9,667,317	85,101
25455	WJZ–TV	9,743,335	9,350,346	82,311
73152	WJZY	4,432,745	4,301,117	37,863
64983	WKAQ–TV[3]	3,697,088	2,731,588	2,969
6104	WKAR–TV	1,693,373	1,689,830	14,876
34171	WKAS	542,308	512,994	4,516
51570	WKBD–TV	5,065,617	5,065,350	44,590
73153	WKBN–TV	4,898,622	4,535,576	39,927
13929	WKBS–TV	1,082,894	937,847	8,256
74424	WKBT–DT	866,325	824,795	7,261
54176	WKBW–TV	2,247,191	2,161,366	19,027
53465	WKCF	4,241,181	4,240,354	37,328
73155	WKEF	3,730,595	3,716,127	32,713
34177	WKGB–TV	413,268	411,587	3,623
34196	WKHA	511,281	400,721	3,528
34207	WKLE	856,237	846,630	7,453
34212	WKMA–TV	524,617	524,035	4,613
71293	WKMG–TV	3,817,673	3,817,673	33,607
34195	WKMJ–TV	1,477,906	1,470,645	12,946
34202	WKMR	463,316	428,462	3,772
34174	WKMU	344,430	344,050	3,029
42061	WKNO	1,645,867	1,642,092	14,455
83931	WKNX–TV	1,684,178	1,459,493	12,848
34205	WKOH	584,645	579,258	5,099
67869	WKOI–TV	3,831,757	3,819,550	33,623
34211	WKON	1,080,274	1,072,320	9,440
18267	WKOP–TV	1,555,654	1,382,098	12,167
64545	WKOW	1,918,224	1,899,746	16,723
21432	WKPC–TV	1,525,919	1,517,701	13,360
65758	WKPD	283,454	282,250	2,485
34200	WKPI–TV	606,666	481,220	4,236
27504	WKPT–TV	1,131,213	887,806	7,815
58341	WKPV[10]	1,132,932	731,199	5,213
11289	WKRC–TV	3,281,914	3,229,223	28,427
73187	WKRG–TV	1,526,600	1,526,075	13,434
73188	WKRN–TV	2,409,767	2,388,588	21,027
34222	WKSO–TV	658,441	642,090	5,652
40902	WKTC	1,387,229	1,386,779	12,208
60654	WKTV	1,573,503	1,342,387	11,817
73195	WKYC	4,180,327	4,124,135	36,305
24914	WKYT–TV	1,174,615	1,156,978	10,185
71861	WKYU–TV	411,448	409,310	3,603
34181	WKZT–TV	1,044,532	1,020,878	8,987
18819	WLAE–TV	1,397,967	1,397,967	12,306
36533	WLAJ	4,100,475	4,063,963	35,775
2710	WLAX	469,017	447,381	3,938
68542	WLBT	948,671	947,857	8,344
39644	WLBZ	373,129	364,346	3,207
69328	WLED–TV	332,718	174,998	1,541
63046	WLEF–TV	200,517	199,188	1,753
73203	WLEX–TV	969,481	964,735	8,493
37806	WLFB	798,916	688,519	6,061
37808	WLFG	1,614,321	1,282,063	11,286
73204	WLFI–TV	2,243,009	2,221,313	19,554
73205	WLFL	3,747,583	3,743,960	32,958
19777	WLII–DT[4 8]	2,801,102	2,153,564	18,958
37503	WLIO	1,067,232	1,050,170	9,245
38336	WLIW	20,027,920	19,717,729	173,575
27696	WLJC–TV	1,401,072	1,281,256	11,279
71645	WLJT–DT	385,493	385,380	3,393
53939	WLKY	1,927,997	1,919,810	16,900
11033	WLLA	2,081,693	2,081,436	18,323
17076	WLMB	2,754,484	2,747,490	24,186
68518	WLMT	1,736,552	1,733,496	15,260
22591	WLNE–TV	6,429,522	6,381,825	56,179

TABLE 7—FY 2022 FULL-SERVICE BROADCAST TELEVISION STATIONS BY CALL SIGN—Continued

Facility Id.	Call sign	Service area population	Terrain limited population	Terrain limited fee amount
74420	WLNS–TV	4,100,475	4,063,963	35,775
73206	WLNY–TV	7,501,199	7,415,578	65,279
84253	WLOO	913,960	912,674	8,034
56537	WLOS	3,086,751	2,544,360	22,398
37732	WLOV–TV	609,526	607,780	5,350
13995	WLOX	1,182,149	1,170,659	10,305
38586	WLPB–TV	1,219,624	1,219,407	10,734
73189	WLPX–TV	1,066,912	1,022,543	9,001
66358	WLRN–TV	5,447,399	5,447,399	47,953
73226	WLS–TV	10,174,464	10,170,757	89,533
73230	WLTV–DT	5,427,398	5,427,398	47,777
37176	WLTX	1,580,677	1,578,645	13,897
37179	WLTZ	689,521	685,358	6,033
21259	WLUC–TV	92,246	85,393	752
4150	WLUK–TV	1,251,563	1,247,414	10,981
73238	WLVI	7,441,208	7,343,735	64,647
36989	WLVT–TV	10,613,847	9,474,797	83,407
3978	WLWC	3,281,532	3,150,875	27,737
46979	WLWT	3,367,381	3,355,009	29,534
54452	WLXI	4,184,851	4,166,318	36,676
55350	WLYH	2,829,585	2,367,000	20,837
43192	WMAB–TV	405,483	399,560	3,517
43170	WMAE–TV	686,076	653,173	5,750
43197	WMAH–TV	1,257,393	1,256,995	11,065
43176	WMAO–TV	369,696	369,343	3,251
47905	WMAQ–TV	9,914,395	9,913,272	87,267
59442	WMAR–TV	9,198,495	9,072,076	79,861
43184	WMAU–TV	642,328	636,504	5,603
43193	WMAV–TV	1,008,339	1,008,208	8,875
43169	WMAW–TV	726,173	715,450	6,298
46991	WMAZ–TV	1,185,678	1,136,616	10,006
66398	WMBB	935,027	914,607	8,051
43952	WMBC–TV	18,706,132	18,458,331	162,489
42121	WMBD–TV	742,729	742,660	6,538
83969	WMBF–TV	445,363	445,363	3,921
60829	WMCF–TV	612,942	609,635	5,367
9739	WMCN–TV	10,448,829	10,049,700	88,468
19184	WMC–TV	2,047,403	2,043,125	17,986
189357	WMDE	6,384,827	6,257,910	55,088
73255	WMDN	278,227	278,018	2,447
16455	WMDT	731,868	731,868	6,443
39656	WMEA–TV	902,755	853,857	7,517
39648	WMEB–TV	511,761	494,574	4,354
70537	WMEC	218,027	217,839	1,918
39649	WMED–TV	30,488	29,577	260
39662	WMEM–TV	71,700	69,981	616
41893	WMFD–TV	1,561,367	1,324,244	11,657
41436	WMFP	5,792,048	5,564,295	48,982
61111	WMGM–TV	807,797	807,797	7,111
43847	WMGT–TV	601,894	601,309	5,293
73263	WMHT	1,719,949	1,550,977	13,653
68545	WMLW–TV	1,843,933	1,843,663	16,230
53819	WMOR–TV	5,394,541	5,394,541	47,488
81503	WMOW	121,150	105,957	933
65944	WMPB	7,279,563	7,190,696	63,300
43168	WMPN–TV	856,237	854,089	7,519
65942	WMPT	8,637,742	8,584,398	75,568
60827	WMPV–TV	1,423,052	1,422,411	12,521
10221	WMSN–TV	1,947,942	1,927,158	16,965
2174	WMTJ[11]	3,143,148	2,365,308	20,822
6870	WMTV	1,548,616	1,545,459	13,605
73288	WMTW	1,940,292	1,658,816	14,603
23935	WMUM–TV	925,814	920,835	8,106
73292	WMUR–TV	5,242,334	5,057,770	44,524
42663	WMVS	3,172,534	3,112,231	27,397
42665	WMVT	3,172,534	3,112,231	27,397
81946	WMWC–TV	946,858	916,989	8,072
56548	WMYA–TV	1,650,798	1,571,594	13,835
74211	WMYD	5,750,989	5,750,873	50,625
20624	WMYT–TV	4,432,745	4,301,117	37,863
25544	WMYV	3,901,915	3,875,210	34,113

TABLE 7—FY 2022 FULL-SERVICE BROADCAST TELEVISION STATIONS BY CALL SIGN—Continued

Facility Id.	Call sign	Service area population	Terrain limited population	Terrain limited fee amount
73310	WNAB	2,176,984	2,166,809	19,074
73311	WNAC–TV	7,310,183	6,959,064	61,261
47535	WNBC	21,952,082	21,399,204	188,377
83965	WNBW–DT	1,400,631	1,396,012	12,289
72307	WNCF	667,683	665,950	5,862
50782	WNCN	3,795,494	3,783,131	33,303
57838	WNCT–TV	1,935,414	1,887,929	16,619
41674	WNDU–TV	1,863,764	1,835,398	16,157
28462	WNDY–TV	2,912,963	2,855,253	25,135
71928	WNED–TV	1,387,961	1,370,480	12,064
60931	WNEH	1,261,482	1,255,218	11,050
41221	WNEM–TV	1,475,094	1,471,908	12,957
49439	WNEO	3,353,869	3,271,369	28,798
73318	WNEP–TV	3,429,213	2,838,000	24,983
18795	WNET	21,113,760	20,615,190	181,476
51864	WNEU	7,135,190	7,067,520	62,215
23942	WNGH–TV	5,744,856	5,595,366	49,256
67802	WNIN	908,275	891,946	7,852
41671	WNIT	1,305,447	1,305,447	11,492
48457	WNJB	20,787,272	20,036,393	176,380
48477	WNJN	20,787,272	20,036,393	176,380
48481	WNJS	7,383,483	7,343,269	64,643
48465	WNJT	7,383,483	7,343,269	64,643
73333	WNJU	21,952,082	21,399,204	188,377
73336	WNJX–TV[2]	1,628,732	1,170,083	2,688
61217	WNKY	379,002	377,357	3,322
71905	WNLO	1,900,503	1,820,106	16,022
4318	WNMU	181,736	179,662	1,582
73344	WNNE	792,551	676,539	5,956
54280	WNOL–TV	1,632,389	1,632,389	14,370
71676	WNPB–TV	2,130,047	1,941,707	17,093
62137	WNPI–DT	167,931	161,748	1,424
41398	WNPT	2,266,543	2,235,316	19,677
28468	WNPX–TV	2,084,890	2,071,017	18,231
61009	WNSC–TV	2,431,154	2,425,044	21,348
61010	WNTV	2,419,841	2,211,019	19,464
16539	WNTZ–TV	344,704	343,849	3,027
7933	WNUV	9,098,694	8,906,508	78,404
9999	WNVC	807,960	690,381	6,077
10019	WNVT	1,721,004	1,712,249	15,073
73354	WNWO–TV	2,872,428	2,872,250	25,284
136751	WNYA	1,923,118	1,651,777	14,541
30303	WNYB	1,785,269	1,756,096	15,459
6048	WNYE–TV	19,414,613	19,180,858	168,849
34329	WNYI	1,627,542	1,338,811	11,786
67784	WNYO–TV	1,430,491	1,409,756	12,410
73363	WNYT	1,679,494	1,516,775	13,352
22206	WNYW	20,075,874	19,753,060	173,886
69618	WOAI–TV	2,525,811	2,513,887	22,130
66804	WOAY–TV	581,486	443,210	3,902
41225	WOFL	4,048,104	4,043,672	35,596
70651	WOGX	1,112,408	1,112,408	9,793
8661	WOI–DT	1,173,757	1,170,432	10,303
39746	WOIO	3,821,233	3,745,335	32,970
71725	WOLE–DT[4]	1,784,094	1,312,984	8,332
73375	WOLF–TV	2,990,646	2,522,858	22,209
60963	WOLO–TV	2,635,715	2,594,980	22,844
36838	WOOD–TV	2,507,053	2,501,084	22,017
67602	WOPX–TV	3,877,863	3,877,805	34,136
64865	WORA–TV[3 13]	3,594,115	2,762,755	24,321
73901	WORO–DT	3,243,301	2,511,742	22,111
60357	WOST	1,193,381	853,762	7,516
66185	WOSU–TV	2,843,651	2,776,901	24,445
131	WOTF–TV	3,451,383	3,451,383	30,383
10212	WOTV	2,368,797	2,368,397	20,849
50147	WOUB–TV	756,762	734,988	6,470
50141	WOUC–TV	1,713,515	1,649,853	14,524
23342	WOWK–TV	1,159,175	1,083,663	9,539
65528	WOWT	1,380,979	1,377,287	12,124
31570	WPAN	1,254,821	1,254,636	11,045
51988	WPBF	3,190,307	3,186,405	28,050

TABLE 7—FY 2022 FULL-SERVICE BROADCAST TELEVISION STATIONS BY CALL SIGN—Continued

Facility Id.	Call sign	Service area population	Terrain limited population	Terrain limited fee amount
21253	WPBN–TV	442,005	430,953	3,794
62136	WPBS–TV	338,448	301,692	2,656
13456	WPBT	5,416,604	5,416,604	47,682
13924	WPCB–TV	2,934,614	2,800,516	24,653
64033	WPCH–TV	5,948,778	5,874,163	51,710
4354	WPCT	195,270	194,869	1,715
69880	WPCW	3,393,365	3,188,441	28,068
17012	WPDE–TV	1,772,233	1,769,553	15,577
52527	WPEC	5,764,571	5,764,571	50,746
84088	WPFO	1,329,690	1,209,873	10,651
54728	WPGA–TV	559,495	559,025	4,921
60820	WPGD–TV	2,355,629	2,343,715	20,632
73875	WPGH–TV	3,236,098	3,121,767	27,481
2942	WPGX	425,098	422,872	3,723
73879	WPHL–TV	10,421,216	10,246,856	90,203
73881	WPIX	20,638,932	20,213,158	177,936
53113	WPLG	5,587,129	5,587,129	49,183
11906	WPMI–TV	1,468,001	1,467,594	12,919
10213	WPMT	2,412,561	2,191,501	19,292
18798	WPNE–TV	1,161,295	1,160,631	10,217
73907	WPNT	3,172,170	3,064,423	26,976
28480	WPPT	10,613,847	9,474,797	83,407
51984	WPPX–TV	8,206,117	7,995,941	70,388
47404	WPRI–TV	7,254,721	6,990,606	61,538
51991	WPSD–TV	883,814	879,213	7,740
12499	WPSG	10,798,264	10,529,460	92,691
66219	WPSU–TV	1,055,133	868,013	7,641
73905	WPTA	1,099,180	1,099,180	9,676
25067	WPTD	3,423,417	3,411,727	30,033
25065	WPTO	2,961,254	2,951,883	25,985
59443	WPTV–TV	5,840,102	5,840,102	51,410
57476	WPTZ	792,551	676,539	5,956
8616	WPVI–TV	11,491,587	11,302,701	99,498
48772	WPWR–TV	9,957,301	9,954,828	87,632
51969	WPXA–TV	6,587,205	6,458,510	56,854
71236	WPXC–TV	1,561,014	1,561,014	13,742
5800	WPXD–TV	5,249,447	5,249,447	46,211
37104	WPXE–TV	3,067,071	3,057,388	26,914
48406	WPXG–TV	2,577,848	2,512,150	22,114
73312	WPXH–TV	1,471,601	1,451,634	12,779
73910	WPXI	3,300,896	3,197,864	28,151
2325	WPXJ–TV	2,357,870	2,289,706	20,156
52628	WPXK–TV	1,801,997	1,577,806	13,889
21729	WPXL–TV	1,639,180	1,639,180	14,430
48608	WPXM–TV	5,153,621	5,153,621	45,367
73356	WPXN–TV	20,878,066	20,454,468	180,061
27290	WPXP–TV	5,565,072	5,565,072	48,989
50063	WPXQ–TV	3,281,532	3,150,875	27,737
70251	WPXR–TV	1,375,640	1,200,331	10,567
40861	WPXS	2,339,305	2,251,498	19,820
53065	WPXT	1,002,128	952,535	8,385
37971	WPXU–TV	700,488	700,488	6,166
67077	WPXV–TV	1,919,794	1,919,794	16,900
74091	WPXW–TV	8,075,268	8,024,342	70,638
21726	WPXX–TV	1,562,675	1,560,834	13,740
73319	WQAD–TV	1,101,012	1,089,523	9,591
65130	WQCW	1,307,345	1,236,020	10,881
71561	WQEC	183,969	183,690	1,617
41315	WQED	3,529,305	3,426,684	30,165
3255	WQHA	3,229,803	1,875,347	16,509
60556	WQHS–DT	3,996,567	3,952,672	34,795
53716	WQLN	602,232	577,633	5,085
52075	WQMY	410,269	254,586	2,241
64550	WQOW	369,066	358,576	3,157
5468	WQPT–TV	941,381	933,107	8,214
64690	WQPX–TV	1,644,283	1,212,587	10,674
52408	WQRF–TV	1,375,774	1,354,979	11,928
2175	WQTO [11]	2,864,201	1,598,365	6,468
8688	WRAL–TV	3,852,675	3,848,801	33,881
10133	WRAY–TV	4,184,851	4,166,318	36,676
64611	WRAZ	3,800,594	3,797,515	33,430

TABLE 7—FY 2022 FULL-SERVICE BROADCAST TELEVISION STATIONS BY CALL SIGN—Continued

Facility Id.	Call sign	Service area population	Terrain limited population	Terrain limited fee amount
136749	WRBJ–TV	1,030,831	1,028,010	9,050
3359	WRBL	1,493,140	1,461,459	12,865
57221	WRBU	2,933,497	2,929,776	25,791
54940	WRBW	4,080,267	4,077,341	35,893
59137	WRCB	1,587,742	1,363,582	12,004
47904	WRC–TV	8,188,601	8,146,696	71,715
54963	WRDC	3,972,477	3,966,864	34,920
55454	WRDQ	3,930,315	3,930,315	34,599
73937	WRDW–TV	1,564,584	1,533,682	13,501
66174	WREG–TV	1,642,307	1,638,585	14,424
61011	WRET–TV	2,419,841	2,211,019	19,464
73940	WREX	2,303,027	2,047,951	18,028
54443	WRFB[13]	2,674,527	1,975,375	2,969
73942	WRGB	1,757,575	1,645,483	14,485
411	WRGT–TV	3,451,036	3,416,078	30,072
74416	WRIC–TV	2,059,152	1,996,075	17,571
61012	WRJA–TV	1,204,291	1,201,900	10,580
412	WRLH–TV	2,017,508	1,959,111	17,246
61013	WRLK–TV	1,229,094	1,228,616	10,816
43870	WRLM	3,960,217	3,945,408	34,731
74156	WRNN–TV	19,853,836	19,615,370	172,674
73964	WROC–TV	1,203,412	1,185,203	10,433
159007	WRPT	110,009	109,937	968
20590	WRPX–TV	2,637,949	2,634,141	23,188
62009	WRSP–TV	1,156,134	1,154,040	10,159
40877	WRTV	2,919,683	2,895,164	25,486
15320	WRUA	2,905,193	2,121,362	18,674
71580	WRXY–TV	1,784,000	1,784,000	15,705
48662	WSAV–TV	1,000,315	1,000,309	8,806
6867	WSAW–TV	652,442	646,386	5,690
36912	WSAZ–TV	1,239,187	1,168,954	10,290
56092	WSBE–TV	7,535,710	7,266,304	63,965
73982	WSBK–TV	7,290,901	7,225,463	63,606
72053	WSBS–TV	42,952	42,952	378
73983	WSBT–TV	1,763,215	1,752,698	15,429
23960	WSB–TV	5,897,425	5,828,269	51,306
69446	WSCG	867,516	867,490	7,637
64971	WSCV	5,465,435	5,465,435	48,112
70536	WSEC	538,090	536,891	4,726
49711	WSEE–TV	613,176	595,476	5,242
21258	WSES	1,829,499	1,796,561	15,815
73988	WSET–TV	1,575,886	1,340,273	11,798
13993	WSFA	1,166,744	1,132,826	9,972
11118	WSFJ–TV	1,675,987	1,667,150	14,676
10203	WSFL–TV	5,344,129	5,344,129	47,044
72871	WSFX–TV	970,833	970,833	8,546
73999	WSIL–TV	672,560	669,176	5,891
4297	WSIU–TV	1,019,939	937,070	8,249
74007	WSJV	1,651,178	1,644,683	14,478
78908	WSKA	546,588	431,354	3,797
74034	WSKG–TV	892,402	633,163	5,574
76324	WSKY–TV	1,934,585	1,934,519	17,030
57840	WSLS–TV	1,447,286	1,277,753	11,248
21737	WSMH	2,339,224	2,327,660	20,490
41232	WSMV–TV	2,447,769	2,404,766	21,169
70119	WSNS–TV	9,914,395	9,913,272	87,267
74070	WSOC–TV	3,706,808	3,638,832	32,033
66391	WSPA–TV	3,388,945	3,227,025	28,408
64352	WSPX–TV	1,298,295	1,174,763	10,341
17611	WSRE	1,354,495	1,353,634	11,916
63867	WSST–TV	331,907	331,601	2,919
60341	WSTE–DT	3,723,967	3,033,272	26,702
21252	WSTM–TV	1,455,586	1,379,393	12,143
11204	WSTR–TV	3,297,280	3,286,795	28,934
19776	WSUR–DT[8]	3,714,790	3,015,529	8,332
2370	WSVI	50,601	50,601	445
63840	WSVN	5,588,748	5,588,748	49,198
73374	WSWB	1,530,002	1,102,316	9,704
28155	WSWG	381,004	380,910	3,353
71680	WSWP–TV	902,592	694,697	6,115
74094	WSYM–TV	1,498,905	1,498,671	13,193

TABLE 7—FY 2022 FULL-SERVICE BROADCAST TELEVISION STATIONS BY CALL SIGN—Continued

Facility Id.	Call sign	Service area population	Terrain limited population	Terrain limited fee amount
73113	WSYR–TV	1,329,977	1,243,098	10,943
40758	WSYT	1,970,721	1,739,071	15,309
56549	WSYX	2,635,937	2,592,420	22,821
65681	WTAE–TV	2,995,755	2,860,979	25,185
23341	WTAJ–TV	1,187,718	948,598	8,351
4685	WTAP–TV	512,358	494,914	4,357
416	WTAT–TV	1,111,476	1,111,476	9,784
67993	WTBY–TV	15,858,470	15,766,438	138,792
29715	WTCE–TV	2,620,599	2,620,599	23,069
65667	WTCI	1,216,209	1,104,698	9,725
67786	WTCT	608,457	607,620	5,349
28954	WTCV[59]	3,254,481	2,500,195	22,009
74422	WTEN	1,902,431	1,613,747	14,206
9881	WTGL	3,707,507	3,707,507	32,637
27245	WTGS	966,519	966,357	8,507
70655	WTHI–TV	928,934	886,846	7,807
70162	WTHR	2,949,339	2,901,633	25,543
147	WTIC–TV	5,318,753	4,707,697	41,442
26681	WTIN–TV[7]	3,714,547	2,898,224	2,688
66536	WTIU	1,570,257	1,569,135	13,813
1002	WTJP–TV	1,947,743	1,907,300	16,790
4593	WTJR	334,527	334,221	2,942
70287	WTJX–TV	135,017	121,498	1,070
47401	WTKR	2,149,376	2,149,375	18,921
82735	WTLF	349,696	349,691	3,078
23486	WTLH	1,065,127	1,065,105	9,376
67781	WTLJ	1,622,365	1,621,227	14,272
65046	WTLV	1,757,600	1,739,021	15,309
1222	WTLW	1,646,714	1,644,206	14,474
74098	WTMJ–TV	3,096,406	3,085,983	27,166
74109	WTNH	7,845,782	7,332,431	64,547
19200	WTNZ	1,699,427	1,513,754	13,326
590	WTOC–TV	993,098	992,658	8,738
74112	WTOG	5,268,364	5,267,177	46,367
4686	WTOK–TV	417,919	412,276	3,629
13992	WTOL	4,184,020	4,174,198	36,745
21254	WTOM–TV	120,369	117,121	1,031
74122	WTOV–TV	3,892,886	3,619,899	31,866
82574	WTPC–TV	2,049,246	2,042,851	17,983
86496	WTPX–TV	255,972	255,791	2,252
6869	WTRF–TV	2,941,511	2,565,375	22,583
67798	WTSF	922,441	851,465	7,495
11290	WTSP	5,506,869	5,489,954	48,328
4108	WTTA	5,583,544	5,576,649	49,091
74137	WTTE	2,690,341	2,650,354	23,331
22207	WTTG	8,101,358	8,049,329	70,858
56526	WTTK	2,844,384	2,825,807	24,876
74138	WTTO	1,877,570	1,844,214	16,235
56523	WTTV	2,522,077	2,518,133	22,167
10802	WTTW	9,729,982	9,729,634	85,650
74148	WTVA	823,492	810,123	7,132
22590	WTVC	1,579,628	1,366,976	12,033
8617	WTVD	3,790,354	3,775,757	33,238
55305	WTVE	5,156,905	5,152,997	45,362
36504	WTVF	2,384,622	2,367,601	20,842
74150	WTVG	4,405,350	4,397,113	38,708
74151	WTVH	1,390,502	1,327,319	11,684
10645	WTVI	2,856,703	2,829,960	24,912
63154	WTVJ	5,458,451	5,458,451	48,051
595	WTVM	1,498,667	1,405,957	12,377
72945	WTVO	1,409,708	1,398,825	12,314
28311	WTVP	678,884	678,539	5,973
51597	WTVQ–DT	989,786	983,552	8,658
57832	WTVR–TV	1,816,197	1,809,035	15,925
16817	WTVS	5,511,091	5,510,837	48,512
68569	WTVT	5,473,148	5,460,179	48,066
3661	WTVW	839,003	834,187	7,343
35575	WTVX	3,157,609	3,157,609	27,796
4152	WTVY	974,532	971,173	8,549
40759	WTVZ–TV	2,156,534	2,156,346	18,982
66908	WTWC–TV	1,061,101	1,061,079	9,341

TABLE 7—FY 2022 FULL-SERVICE BROADCAST TELEVISION STATIONS BY CALL SIGN—Continued

Facility Id.	Call sign	Service area population	Terrain limited population	Terrain limited fee amount
20426	WTWO	737,341	731,294	6,438
81692	WTWV	1,527,511	1,526,625	13,439
51568	WTXF–TV	10,784,256	10,492,549	92,366
41065	WTXL–TV	1,054,514	1,054,322	9,281
8532	WUAB	3,821,233	3,745,335	32,970
12855	WUCF–TV	3,707,507	3,707,507	32,637
36395	WUCW	3,664,480	3,657,236	32,195
69440	WUFT	1,372,142	1,372,142	12,079
413	WUHF	1,152,580	1,147,972	10,106
8156	WUJA	2,638,361	1,977,410	17,407
69080	WUNC–TV	4,184,851	4,166,318	36,676
69292	WUND–TV	1,504,532	1,504,532	13,244
69114	WUNE–TV	3,146,865	2,625,942	23,116
69300	WUNF–TV	2,625,583	2,331,723	20,526
69124	WUNG–TV	3,605,143	3,588,220	31,587
60551	WUNI	7,209,571	7,084,349	62,364
69332	WUNJ–TV	1,116,458	1,116,458	9,828
69149	WUNK–TV	1,991,039	1,985,696	17,480
69360	WUNL–TV	3,055,263	2,834,274	24,950
69444	WUNM–TV	1,357,346	1,357,346	11,949
69397	WUNP–TV	1,402,186	1,393,524	12,267
69416	WUNU	1,202,495	1,201,481	10,577
83822	WUNW	1,109,237	570,072	5,018
6900	WUPA	5,966,454	5,888,379	51,835
13938	WUPL	1,721,320	1,721,320	15,153
10897	WUPV	1,933,664	1,914,643	16,855
19190	WUPW	2,100,914	2,099,572	18,483
23128	WUPX–TV	1,102,435	1,089,118	9,588
65593	WUSA	8,750,706	8,446,074	74,351
4301	WUSI–TV	339,507	339,507	2,989
60552	WUTB	8,523,983	8,381,042	73,778
30577	WUTF–TV	7,918,927	7,709,189	67,864
57837	WUTR	526,114	481,957	4,243
415	WUTV	1,589,376	1,557,474	13,710
16517	WUVC–DT	3,768,817	3,748,841	33,001
48813	WUVG–DT	6,029,495	5,965,975	52,518
3072	WUVN	1,233,568	1,157,140	10,186
60560	WUVP–DT	10,421,216	10,246,856	90,203
9971	WUXP–TV	2,316,872	2,305,293	20,293
417	WVAH–TV	1,373,555	1,295,383	11,403
23947	WVAN–TV	1,026,862	1,025,950	9,031
65387	WVBT	1,885,169	1,885,169	16,595
72342	WVCY–TV	3,111,641	3,102,097	27,308
60559	WVEA–TV	4,553,004	4,552,113	40,072
74167	WVEC	2,098,679	2,092,868	18,424
5802	WVEN–TV	3,921,016	3,919,361	34,502
61573	WVEO[5]	1,091,825	757,978	5,281
69946	WVER	888,756	758,441	6,677
10976	WVFX	731,193	609,763	5,368
47929	WVIA–TV	3,429,213	2,838,000	24,983
3667	WVII–TV	368,022	346,874	3,054
70309	WVIR–TV	1,945,637	1,908,395	16,800
74170	WVIT	5,846,093	5,357,639	47,163
18753	WVIZ	3,695,223	3,689,173	32,476
70021	WVLA–TV	1,897,179	1,897,007	16,699
81750	WVLR	1,412,728	1,300,554	11,449
35908	WVLT–TV	1,888,607	1,633,633	14,381
74169	WVNS–TV	916,451	588,963	5,185
11259	WVNY	742,579	659,270	5,804
29000	WVOZ–TV[9]	1,132,932	731,199	5,281
71657	WVPB–TV	992,798	959,526	8,447
60111	WVPT	767,268	642,173	5,653
70491	WVPX–TV	4,147,298	4,114,920	36,224
66378	WVPY	756,696	632,649	5,569
67190	WVSN	2,948,832	2,137,333	18,815
69943	WVTA	888,756	758,441	6,677
69940	WVTB	455,880	257,445	2,266
74173	WVTM–TV	2,009,346	1,940,153	17,079
74174	WVTV	3,091,132	3,083,108	27,141
77496	WVUA	2,209,921	2,160,101	19,015
4149	WVUE–DT	1,658,125	1,658,125	14,596

TABLE 7—FY 2022 FULL-SERVICE BROADCAST TELEVISION STATIONS BY CALL SIGN—Continued

Facility Id.	Call sign	Service area population	Terrain limited population	Terrain limited fee amount
4329	WVUT	273,293	273,215	2,405
74176	WVVA	1,037,632	722,666	6,362
3113	WVXF	85,191	78,556	692
12033	WWAY	1,208,625	1,208,625	10,640
30833	WWBT	1,924,502	1,892,842	16,663
20295	WWCP–TV	2,811,278	2,548,691	22,436
24812	WWCW	1,390,985	1,212,308	10,672
23671	WWDP	5,792,048	5,564,295	48,982
21158	WWHO	2,762,344	2,721,504	23,957
14682	WWJE–DT	7,209,571	7,084,349	62,364
72123	WWJ–TV	5,562,031	5,561,777	48,960
166512	WWJX	518,866	518,846	4,567
6868	WWLP	3,838,272	3,077,800	27,094
74192	WWL–TV	1,788,624	1,788,624	15,745
3133	WWMB	1,547,974	1,544,778	13,599
74195	WWMT	2,538,485	2,531,309	22,283
68851	WWNY–TV	375,600	346,623	3,051
74197	WWOR–TV	19,853,836	19,615,370	172,674
65943	WWPB	3,197,858	2,775,966	24,437
23264	WWPX–TV	2,299,441	2,231,612	19,645
68547	WWRS–TV	2,324,155	2,321,066	20,432
61251	WWSB	3,340,133	3,340,133	29,403
23142	WWSI	11,269,831	11,098,540	97,700
16747	WWTI	196,531	190,097	1,673
998	WWTO–TV	5,613,737	5,613,737	49,418
26994	WWTV	1,034,174	1,022,322	9,000
84214	WWTW	1,527,511	1,526,625	13,439
26993	WWUP–TV	116,638	110,592	974
23338	WXBU	4,030,693	3,538,096	31,146
61504	WXCW	1,749,847	1,749,847	15,404
61084	WXEL–TV	5,416,604	5,416,604	47,682
60539	WXFT–DT	10,174,464	10,170,757	89,533
23929	WXGA–TV	608,494	606,849	5,342
51163	WXIA–TV	6,179,680	6,035,625	53,132
53921	WXII–TV	3,630,551	3,299,114	29,042
146	WXIN	2,836,532	2,814,815	24,779
39738	WXIX–TV	2,911,054	2,900,875	25,536
414	WXLV–TV	4,364,244	4,334,365	38,155
68433	WXMI	1,988,970	1,988,589	17,506
64549	WXOW	425,378	413,264	3,638
6601	WXPX–TV	4,594,588	4,592,639	40,429
74215	WXTV–DT	20,362,721	19,974,644	175,837
12472	WXTX	699,095	694,837	6,117
11970	WXXA–TV	1,680,670	1,537,868	13,538
57274	WXXI–TV	1,184,860	1,168,696	10,288
53517	WXXV–TV	1,191,123	1,189,584	10,472
10267	WXYZ–TV	5,622,543	5,622,140	49,492
12279	WYCC	9,729,982	9,729,634	85,650
77515	WYCI	35,873	26,508	233
70149	WYCW	3,388,945	3,227,025	28,408
62219	WYDC	560,266	449,486	3,957
18783	WYDN	2,577,848	2,512,150	22,114
35582	WYDO	1,330,728	1,330,728	11,714
25090	WYES–TV	1,872,245	1,872,059	16,480
53905	WYFF	2,626,363	2,416,551	21,273
49803	WYIN	6,956,141	6,956,141	61,235
24915	WYMT–TV	1,180,276	863,881	7,605
17010	WYOU	2,879,196	2,226,883	19,603
77789	WYOW	91,839	91,311	804
13933	WYPX–TV	1,529,500	1,413,583	12,444
4693	WYTV	4,898,622	4,535,576	39,927
5875	WYZZ–TV	1,042,140	1,036,721	9,126
15507	WZBJ	1,626,017	1,435,762	12,639
28119	WZDX	1,596,771	1,514,654	13,333
70493	WZME	5,996,408	5,544,708	48,810
81448	WZMQ	73,423	72,945	642
71871	WZPX–TV	2,039,157	2,039,157	17,951
136750	WZRB	952,279	951,693	8,378
418	WZTV	2,312,658	2,301,187	20,257
83270	WZVI	76,992	75,863	668
19183	WZVN–TV	1,981,488	1,981,488	17,443

TABLE 7—FY 2022 FULL-SERVICE BROADCAST TELEVISION STATIONS BY CALL SIGN—Continued

Facility Id.	Call sign	Service area population	Terrain limited population	Terrain limited fee amount
49713	WZZM	1,574,546	1,548,835	13,634

[1] Call signs WIPM and WIPR are stations in Puerto Rico that are linked together with a total fee of $27,290.
[2] Call signs WNJX and WAPA are stations in Puerto Rico that are linked together with a total fee of $27,290.
[3] Call signs WKAQ and WORA are stations in Puerto Rico that are linked together with a total fee of $27,290.
[4] Call signs WOLE and WLII are stations in Puerto Rico that are linked together with a total fee of $27,290.
[5] Call signs WVEO and WTCV are stations in Puerto Rico that are linked together with a total fee of $27,290.
[6] Call signs WJPX and WJWN are stations in Puerto Rico that are linked together with a total fee of $27,290.
[7] Call signs WAPA and WTIN are stations in Puerto Rico that are linked together with a total fee of $27,290.
[8] Call signs WSUR and WLII are stations in Puerto Rico that are linked together with a total fee of $27,290.
[9] Call signs WVOZ and WTCV are stations in Puerto Rico that are linked together with a total fee of $27,290.
[10] Call signs WJPX and WKPV are stations in Puerto Rico that are linked together with a total fee of $27,290.
[11] Call signs WMTJ and WQTO are stations in Puerto Rico that are linked together with a total fee of $27,290.
[12] Call signs WIRS and WJPX are stations in Puerto Rico that are linked together with a total fee of $27,290.
[13] Call signs WRFB and WORA are stations in Puerto Rico that are linked together with a total fee of $27,290.

Regulatory fees for the categories shaded in gray are collected by the Commission in advance to cover the term of the license and are submitted at the time the application is filed.

TABLE 8—FY 2021 SCHEDULE OF REGULATORY FEES

Fee category	Annual regulatory fee (U.S. $s)
PLMRS (per license) (Exclusive Use) (47 CFR part 90)	25.
Microwave (per license) (47 CFR part 101)	25.
Marine (Ship) (per station) (47 CFR part 80)	15.
Marine (Coast) (per license) (47 CFR part 80)	40.
Rural Radio (47 CFR part 22) (previously listed under the Land Mobile category)	10.
PLMRS (Shared Use) (per license) (47 CFR part 90)	10.
Aviation (Aircraft) (per station) (47 CFR part 87)	10.
Aviation (Ground) (per license) (47 CFR part 87)	20.
CMRS Mobile/Cellular Services (per unit) (47 CFR parts 20, 22, 24, 27, 80, and 90) (Includes Non-Geographic telephone numbers).	.15.
CMRS Messaging Services (per unit) (47 CFR parts 20, 22, 24, and 90)	.08.
Broadband Radio Service (formerly MMDS/MDS) (per license) (47 CFR part 27)	605.
Local Multipoint Distribution Service (per call sign) (47 CFR part 101)	605.
AM Radio Construction Permits	610.
FM Radio Construction Permits	1,070.
AM and FM Broadcast Radio Station Fees	See Table Below.
Digital TV (47 CFR part 73) VHF and UHF Commercial Fee Factor	$.007793.
	See Table 7 for fee amounts due, also available at *https://www.fcc.gov/licensing-databases/fees/regulatory-fees.*
Digital TV Construction Permits	5,100.
Low Power TV, Class A TV, TV/FM Translators & FM Boosters (47 CFR part 74)	320.
CARS (47 CFR part 78)	1,555.
Cable Television Systems (per subscriber) (47 CFR part 76), Including IPTV (per subscriber) and Direct Broadcast Satellite (DBS) (per subscriber).	.98.
Interstate Telecommunication Service Providers (per revenue dollar)	.00400.
Toll Free (per toll free subscriber) (47 CFR 52.101(f))	.12.
Earth Stations (47 CFR part 25)	595.
Space Stations (per operational station in geostationary orbit) (47 CFR part 25) also includes DBS Service (per operational station) (47 CFR part 100).	116,855.
Space Stations (per operational system in non-geostationary orbit) (47 CFR part 25) (Other)	343,555.
Space Stations (per operational system in non-geostationary orbit) (47 CFR part 25) (Less Complex)	122,695.
International Bearer Circuits—Terrestrial/Satellites (per Gbps circuit)	43.
Submarine Cable Landing Licenses Fee (per cable system)	See Table Below.

FY 2021 RADIO STATION REGULATORY FEES

Population served	AM Class A	AM Class B	AM Class C	AM Class D	FM Classes A, B1 & C3	FM Classes B, C, C0, C1 & C2
<25,000	$975	$700	$610	$670	$1,070	$1,220
25,001–75,000	1,465	1,050	915	1,000	1,605	1,830
75,001–150,000	2,195	1,575	1,375	1,510	2,410	2,745
150,001–500,000	3,295	2,365	2,060	2,265	3,615	4,125

FY 2021 RADIO STATION REGULATORY FEES—Continued

Population served	AM Class A	AM Class B	AM Class C	AM Class D	FM Classes A, B1 & C3	FM Classes B, C, C0, C1 & C2
500,001–1,200,000	4,935	3,540	3,085	3,390	5,415	6,175
1,200,001–3,000,000	7,410	5,320	4,635	5,090	8,130	9,270
3,000,001–6,000,000	11,105	7,975	6,950	7,630	12,185	13,895
>6,000,000	16,665	11,965	10,425	11,450	18,285	20,850

FY 2021 INTERNATIONAL BEARER CIRCUITS—SUBMARINE CABLE SYSTEMS

Submarine cable systems (capacity as of December 31, 2020)	Fee ratio (units)	FY 2021 regulatory fees
Less than 50 Gbps	.0625	$9,495
50 Gbps or greater, but less than 250 Gbps	.125	18,990
250 Gbps or greater, but less than 1,500 Gbps	.25	37,980
1,500 Gbps or greater, but less than 3,500 Gbps	.5	75,955
3,500 Gbps or greater, but less than 6,500 Gbps	1.0	151,910
6,500 Gbps or greater	2.0	303,820

VI. Initial Regulatory Flexibility Analysis

1. As required by the Regulatory Flexibility Act of 1980, as amended (RFA) the Commission prepared this Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities by the policies and rules proposed in the *NPRM.* Written comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadline for comments on the *NPRM.* The Commission will send a copy of the *NPRM,* including the IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA). In addition, the NPRM and IRFA (or summaries thereof) will be published in the **Federal Register**.

A. Need for, and Objectives of, the Proposed Rules

2. The Commission is required by Congress to assess regulatory fees each year in an amount that can reasonably be expected to equal the amount of its annual appropriation. For fiscal year (FY) 2022, the Commission must recover $381,950,000, as set forth in the FY 2022 Appropriations Act. The objective of the *NPRM* is to propose the regulatory fees to be paid by the regulatory fee payors in the Commission's core bureaus (Media Bureau, Wireless Telecommunications Bureau, Wireline Competition Bureau, and International Bureau) by the end of the fiscal year for FY 2022 equal to the full amount of the annual appropriation, and to seek comment on the proposed fees. Accordingly, in the *NPRM,* we seek comment on the Commission's historic methodology for calculating regulatory fees as required by section 9 of the Communications Act of 1934, as amended (Communications Act), and on the schedule of FY 2022 regulatory fees as set forth in Tables 2 and 3 of the *NPRM.* We also seek comment on several other issues related to the collection of regulatory fees: (i) continuing to use our methodology for calculating television broadcaster regulatory fees based on population by station contour; (ii) the proposed regulatory fee rates for the categories of small satellite, ''NGSO—less complex,'' and ''NGSO—Other'' space stations; (iii) calculating the costs of collection of regulatory fees in establishing the annual de minimis threshold; and (iv) how our proposals may promote or inhibit advances in diversity, equity, inclusion, and accessibility.

B. Legal Basis

3. This action, including publication of proposed rules, is authorized under sections (4)(i) and (j), 159, 159A, and 303(r) of the Communications Act of 1934, as amended.

C. Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

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

5. *Small Businesses, Small Organizations, Small Governmental Jurisdictions.* Our actions, over time, may affect small entities that are not easily categorized at present. We therefore describe here, at the outset, three broad groups of small entities that could be directly affected herein. First, while there are industry specific size standards for small businesses that are used in the regulatory flexibility analysis, according to data from the Small Business Administration's (SBA) Office of Advocacy, in general a small business is an independent business having fewer than 500 employees. These types of small businesses represent 99.9% of all businesses in the United States, which translates to 30.7 million businesses.

6. Next, the type of small entity described as a ''small organization'' is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' The Internal Revenue Service (IRS) uses a revenue benchmark of $50,000 or less to delineate its annual electronic filing requirements for small exempt organizations. Nationwide, for tax year 2018, there were approximately 571,709 small exempt organizations in the U.S. reporting revenues of $50,000 or less according to the registration and tax data for exempt organizations available from the IRS.

7. Finally, the small entity described as a ''small governmental jurisdiction'' is defined generally as ''governments of cities, counties, towns, townships, villages, school districts, or special

districts, with a population of less than fifty thousand.'' U.S. Census Bureau data from the 2017 Census of Governments indicate that there were 90,075 local governmental jurisdictions consisting of general purpose governments and special purpose governments in the United States. Of this number there were 36,931 general purpose governments (county, municipal and town or township) with populations of less than 50,000 and 12,040 special purpose governments—independent school districts with enrollment populations of less than 5ll governmental jurisdictions.''

8. *Wired Telecommunications Carriers.* The U.S. Census Bureau defines this industry as establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired communications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services, wired (cable) audio and video programming distribution, and wired broadband internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry. Wired Telecommunications Carriers are also referred to as wireline carriers or fixed local service providers.

9. The SBA small business size standard for Wired Telecommunications Carriers classifies firms having 1,500 or fewer employees as small. U.S. Census Bureau data for 2017 shows that there were 3,054 firms that operated in this industry for the entire year. Of this number, 2,964 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2021 Universal Service Monitoring Report, as of December 31, 2020, there were 5,183 providers that reported they were engaged in the provision of fixed local services. Of these providers, the Commission estimates that 4,737 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

10. *Local Exchange Carriers (LECs).* Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to local exchange services. Providers of these services include both incumbent and competitive local exchange service providers. Wired Telecommunications Carriers is the closest industry with a SBA small business size standard. Wired Telecommunications Carriers are also referred to as wireline carriers or fixed local service providers. The SBA small business size standard for Wired Telecommunications Carriers classifies firms having 1,500 or fewer employees as small. U.S. Census Bureau data for 2017 shows that there were 3,054 firms that operated in this industry for the entire year. Of this number, 2,964 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2021 Universal Service Monitoring Report, as of December 31, 2020, there were 5,183 providers that reported they were fixed local exchange service providers. Of these providers, the Commission estimates that 4,737 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

11. *Incumbent Local Exchange Carriers (Incumbent LECs).* Neither the Commission nor the SBA have developed a small business size standard specifically for incumbent local exchange carriers. Wired Telecommunications Carriers is the closest industry with an SBA small business size standard. The SBA small business size standard for Wired Telecommunications Carriers classifies firms having 1,500 or fewer employees as small. U.S. Census Bureau data for 2017 shows that there were 3,054 firms in this industry that operated for the entire year. Of this number, 2,964 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2021 Universal Service Monitoring Report, as of December 31, 2020, there were 1,227 providers that reported they were incumbent local exchange service providers. Of these providers, the Commission estimates that 929 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, the Commission estimates that the majority of incumbent local exchange carriers can be considered small entities.

12. *Competitive Local Exchange Carriers (LECs).* Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to local exchange services. Providers of these services include several types of competitive local exchange service providers. Wired Telecommunications Carriers is the closest industry with an SBA small business size standard. The SBA small business size standard for Wired Telecommunications Carriers classifies firms having 1,500 or fewer employees as small. U.S. Census Bureau data for 2017 shows that there were 3,054 firms that operated in this industry for the entire year. Of this number, 2,964 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2021 Universal Service Monitoring Report, as of December 31, 2020, there were 3,956 providers that reported they were competitive local exchange service providers. Of these providers, the Commission estimates that 3,808 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

13. *Interexchange Carriers (IXCs).* Neither the Commission nor the SBA have developed a small business size standard specifically for Interexchange Carriers. Wired Telecommunications Carriers is the closest industry with an SBA small business size standard. The SBA small business size standard for Wired Telecommunications Carriers classifies firms having 1,500 or fewer employees as small. U.S. Census Bureau data for 2017 shows that there were 3,054 firms that operated in this industry for the entire year. Of this number, 2,964 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2021 Universal Service Monitoring Report, as of December 31, 2020, there were 151 providers that reported they were engaged in the provision of interexchange services. Of these providers, the Commission estimates that 131 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, the Commission estimates that the majority of providers in this industry can be considered small entities.

14. *Prepaid Calling Card Providers.* Neither the Commission nor the SBA has developed a small business size standard specifically for prepaid calling card providers. Telecommunications Resellers is the closest industry with an SBA small business size standard. The Telecommunications Resellers industry comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and reselling wired and wireless telecommunications services (except satellite) to businesses and households.

Establishments in this industry resell telecommunications; they do not operate transmission facilities and infrastructure. Mobile virtual network operators (MVNOs) are included in this industry. The SBA small business size standard for Telecommunications Resellers classifies a business as small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2017 shows that 1,386 firms in this industry provided resale services for the entire year. Of that number, 1,375 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2021 Universal Service Monitoring Report, as of December 31, 2020, there were 58 providers that reported they were engaged in the provision of payphone services. Of these providers, the Commission estimates that 57 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

15. *Local Resellers.* Neither the Commission nor the SBA have developed a small business size standard specifically for Local Resellers. Telecommunications Resellers is the closest industry with an SBA small business size standard. The Telecommunications Resellers industry comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and reselling wired and wireless telecommunications services (except satellite) to businesses and households. Establishments in this industry resell telecommunications; they do not operate transmission facilities and infrastructure. Mobile virtual network operators (MVNOs) are included in this industry. The SBA small business size standard for Telecommunications Resellers classifies a business as small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2017 shows that 1,386 firms in this industry provided resale services for the entire year. Of that number, 1,375 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2021 Universal Service Monitoring Report, as of December 31, 2020, there were 293 providers that reported they were engaged in the provision of local resale services. Of these providers, the Commission estimates that 289 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

16. *Toll Resellers.* Neither the Commission nor the SBA have developed a small business size standard specifically for Toll Resellers. Telecommunications Resellers is the closest industry with an SBA small business size standard. The Telecommunications Resellers industry comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and reselling wired and wireless telecommunications services (except satellite) to businesses and households. Establishments in this industry resell telecommunications; they do not operate transmission facilities and infrastructure. Mobile virtual network operators (MVNOs) are included in this industry. The SBA small business size standard for Telecommunications Resellers classifies a business as small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2017 shows that 1,386 firms in this industry provided resale services for the entire year. Of that number, 1,375 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2021 Universal Service Monitoring Report, as of December 31, 2020, there were 518 providers that reported they were engaged in the provision of toll services. Of these providers, the Commission estimates that 495 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

17. *Other Toll Carriers.* Neither the Commission nor the SBA has developed a definition for small businesses specifically applicable to Other Toll Carriers. This category includes toll carriers that do not fall within the categories of interexchange carriers, operator service providers, prepaid calling card providers, satellite service carriers, or toll resellers. Wired Telecommunications Carriers is the closest industry with an SBA small business size standard. The SBA small business size standard for Wired Telecommunications Carriers classifies firms having 1,500 or fewer employees as small. U.S. Census Bureau data for 2017 shows that there were 3,054 firms in this industry that operated for the entire year. Of this number, 2,964 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2021 Universal Service Monitoring Report, as of December 31, 2020, there were 115 providers that reported they were engaged in the provision of other toll services. Of these providers, the Commission estimates that 113 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

18. *Wireless Telecommunications Carriers (except Satellite).* This industry comprises establishments engaged in operating and maintaining switching and transmission facilities to provide communications via the airwaves. Establishments in this industry have spectrum licenses and provide services using that spectrum, such as cellular services, paging services, wireless internet access, and wireless video services. The SBA size standard for this industry classifies a business as small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2017 shows that there were 2,893 firms in this industry that operated for the entire year. Of that number, 2,837 firms employed fewer than 250 employees. Additionally, based on Commission data in the 2021 Universal Service Monitoring Report, as of December 31, 2020, there were 797 providers that reported they were engaged in the provision of wireless services. Of these providers, the Commission estimates that 715 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

19. *Television Broadcasting.* This industry is comprised of ''establishments primarily engaged in broadcasting images together with sound.'' These establishments operate television broadcast studios and facilities for the programming and transmission of programs to the public. These establishments also produce or transmit visual programming to affiliated broadcast television stations, which in turn broadcast the programs to the public on a predetermined schedule. Programming may originate in their own studio, from an affiliated network, or from external sources. The SBA small business size standard for this industry classifies businesses having $41.5 million or less in annual receipts as small. The 2017 U.S. Census Bureau data indicates that 744 firms in this industry operated for the entire year. Of that number, 657 firms had revenue of less than $25,000,000. Based on this data we estimate that the majority of television broadcasters are small entities under the SBA small business size standard.

20. The Commission estimates that as of September 2021, there were 1,374 licensed commercial television stations, 384 licensed noncommercial educational (NCE) television stations,

2,276 low power television stations, including Class A stations (LPTV) and 3,106 TV translator stations. The Commission however does not compile, and otherwise does not have access to financial information for these television broadcast stations that would permit it to determine how many of these stations qualify as small entities under the SBA small business size standard. Nevertheless, given the SBA's large annual receipts threshold for this industry and the nature of television station licensees, we presume that all of these entities qualify as small entities under the above SBA small business size standard.

21. *Radio Stations.* This industry is comprised of ''establishments primarily engaged in broadcasting aural programs by radio to the public.'' Programming may originate in their own studio, from an affiliated network, or from external sources. The SBA small business size standard for this industry classifies firms having $41.5 million or less in annual receipts as small. U.S. Census Bureau data for 2017 shows that 2,963 firms operated in this industry during that year. Of this number, 1,879 firms operated with revenue of less than $25 million per year. Based on this data and the SBA's small business size standard, we estimate a majority of such entities are small entities.

22. The Commission estimates that as of September 2021, there were 4,519 licensed commercial AM radio stations, 6,682 licensed commercial FM radio stations and 4,211 licensed noncommercial (NCE) FM radio stations. The Commission however does not compile, and otherwise does not have access to financial information for these radio stations that would permit it to determine how many of these stations qualify as small entities under the SBA small business size standard. Nevertheless, given the SBA's large annual receipts threshold for this industry and the nature of radio station licensees, we presume that all of these entities qualify as small entities under the above SBA small business size standard.

23. *Cable Companies and Systems (Rate Regulation).* The Commission has developed its own small business size standard for the purpose of cable rate regulation. Under the Commission's rules, a ''small cable company'' is one serving 400,000 or fewer subscribers nationwide. Based on available data, as of December 2020, there were approximately 45,308,192 basic cable video subscribers in the top Cable multiple system operators (MSOs) in the United States. Only five cable operators serving cable video subscribers in the top Cable MSOs had more than 400,000 subscribers. Accordingly, the Commission estimates that the majority of cable operators are small.

24. *Cable System Operators (Telecom Act Standard).* The Communications Act of 1934, as amended, contains a size standard for small cable system operators, which classifies ''a cable operator that, directly or through an affiliate, serves in the aggregate fewer than one percent of all subscribers in the United States and is not affiliated with any entity or entities whose gross annual revenues in the aggregate exceed $250,000,000,'' as small. As of December 2020, there were approximately 45,308,192 basic cable video subscribers in the top Cable MSOs in the United States. Accordingly, an operator serving fewer than 453,082 subscribers shall be deemed a small operator if its annual revenues, when combined with the total annual revenues of all its affiliates, do not exceed $250 million in the aggregate. Based on available data, all but five of the cable operators in the Top Cable MSOs have less than 453,082 subscribers and can be considered small entities under this size standard. We note however, that the Commission neither requests nor collects information on whether cable system operators are affiliated with entities whose gross annual revenues exceed $250 million. Therefore, we are unable at this time to estimate with greater precision the number of cable system operators that would qualify as small cable operators under the definition in the Communications Act.

25. *Direct Broadcast Satellite (DBS) Service.* DBS service is a nationally distributed subscription service that delivers video and audio programming via satellite to a small parabolic ''dish'' antenna at the subscriber's location. DBS is included in the Wired Telecommunications Carriers industry which comprises establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired telecommunications networks. Transmission facilities may be based on a single technology or combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including voice over internet protocol (VoIP) services, wired (cable) audio and video programming distribution; and wired broadband internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry.

26. The SBA small business size standard for Wired Telecommunications Carriers classifies firms having 1,500 or fewer employees as small. U.S. Census Bureau data for 2017 shows that 3,054 firms operated in this industry for the entire year. Of this number, 2,964 firms operated with fewer than 250 employees. Based on this data, the majority of firms in this industry can be considered small under the SBA small business size standard. According to Commission data however, only two entities provide DBS service—DIRECTV (owned by AT&T) and DISH Network, which require a great deal of capital for operation. DIRECTV and DISH Network both exceed the SBA size standard for classification as a small business. Therefore, we must conclude based on internally developed Commission data, in general DBS service is provided only by large firms.

27. *Satellite Telecommunications.* This industry comprises firms ''primarily engaged in providing telecommunications services to other establishments in the telecommunications and broadcasting industries by forwarding and receiving communications signals via a system of satellites or reselling satellite telecommunications.'' Satellite telecommunications service providers include satellite and earth station operators. The SBA small business size standard for this industry classifies a business with $35 million or less in annual receipts as small. U.S. Census Bureau data for 2017 shows that 275 firms in this industry operated for the entire year. Of this number, 242 firms had revenue of less than $25 million. Additionally, based on Commission data in the 2021 Universal Service Monitoring Report, as of December 31, 2020, there were 71 providers that reported they were engaged in the provision of satellite telecommunications services. Of these providers, the Commission estimates that approximately 48 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, a little more than of these providers can be considered small entities.

28. *All Other Telecommunications.* This industry is comprised of establishments primarily engaged in providing specialized telecommunications services, such as satellite tracking, communications telemetry, and radar station operation. This industry also includes

establishments primarily engaged in providing satellite terminal stations and associated facilities connected with one or more terrestrial systems and capable of transmitting telecommunications to, and receiving telecommunications from, satellite systems. Providers of internet services (*e.g.* dial-up internet service providers (ISPs)) or VoIP services, via client-supplied telecommunications connections are also included in this industry. The SBA small business size standard for this industry classifies firms with annual receipts of $35 million or less as small. U.S. Census Bureau data for 2017 shows that there were 1,079 firms in this industry that operated for the entire year. Of those firms, 1,039 had revenue of less than $25 million. Based on this data, the Commission estimates that the majority of ''All Other Telecommunications'' firms can be considered small.

29. *RespOrgs.* Responsible Organizations, or RespOrgs (also referred to as Toll-Free Number (TFN) providers), are entities chosen by toll free subscribers to manage and administer the appropriate records in the toll-free Service Management System for the toll-free subscriber. Based on information on the website of SOMOS, the entity that maintains a registry of Toll-Free Number providers (SMS/800 TFN Registry) for the more than 42 million Toll-Free numbers in North America, and the TSS Registry, a centralized registry for the use of Toll-Free Numbers in text messaging and multimedia services, there were approximately 446 registered RespOrgs/Toll-Free Number providers in July 2021. RespOrgs are often wireline carriers, however they can be include non-carrier entities. Accordingly, the description below for RespOrgs include both Carrier RespOrgs and Non-Carrier RespOrgs.

30. *Carrier RespOrgs.* Neither the Commission nor the SBA have developed a small business size standard for Carrier RespOrgs. *Wired Telecommunications Carriers,* and *Wireless Telecommunications Carriers (except Satellite)* are the closest industries with an SBA small business size applicable to Carrier RespOrgs.

31. *Wired Telecommunications Carriers* are establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired communications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services, wired (cable) audio and video programming distribution, and wired broadband internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry. The SBA small business size standard for this industry classifies a business as small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2017 shows that there were 3,054 firms that operated for the entire year. Of this number, 2,964 firms operated with fewer than 250 employees. Based on that data, we conclude that the majority of Carrier RespOrgs that operated with wireline-based technology are small.

32. *Wireless Telecommunications Carriers (except Satellite)* engage in operating and maintaining switching and transmission facilities to provide communications via the airwaves. Establishments in this industry have spectrum licenses and provide services using that spectrum, such as cellular services, paging services, wireless internet access, and wireless video services. The SBA small business size standard for this industry classifies a business as small if it has 1,500 or fewer employees. For this industry, U.S. Census Bureau data for 2017 shows that there were 2,893 firms that operated for the entire year. Of this number, 2,837 firms employed fewer than 250 employees. Based on this data, we conclude that the majority of Carrier RespOrgs that operated with wireless-based technology are small.

33. *Non-Carrier RespOrgs.* Neither the Commission, nor the SBA have developed a small business size standard Non-Carrier RespOrgs. *Other Services Related to Advertising* and *Other Management Consulting Services*'' are the closest industries with an SBA small business size applicable to Non-Carrier RespOrgs.

34. The *Other Services Related to Advertising* industry contains establishments primarily engaged in providing advertising services (except advertising agency services, public relations agency services, media buying agency services, media representative services, display advertising services, direct mail advertising services, advertising material distribution services, and marketing consulting services). The SBA small business size standard for this industry classifies a business as small that has annual receipts of $16.5 million or less. U.S. Census Bureau data for 2017 shows that 5,650 firms operated in this industry for the entire year. Of that number, 3,693 firms operated with revenue of less than $10 million. Based on this data, we conclude that a majority of non-carrier RespOrgs who provide TFN-related management consulting services are small.

35. The *Other Management Consulting Services* industry contains establishments primarily engaged in providing management consulting services (except administrative and general management consulting; human resources consulting; marketing consulting; or process, physical distribution, and logistics consulting). Establishments providing telecommunications or utilities management consulting services are included in this industry. The SBA small business size standard for this industry classifies a business as small if it has annual receipts of $16.5 million or less. U.S. Census Bureau data for 2017 shows that 4,696 firms operated in this industry for the entire year. Of that number, 3,700 firms had revenue of less than $10 million. Based on this data, we conclude that a majority of non-carrier RespOrgs who provide TFN-related management consulting services are small.

D. Description of Projected Reporting, Recordkeeping and Other Compliance Requirements for Small Entities

36. The *NPRM* does not propose any changes to the Commission's current information collection, reporting, recordkeeping, or compliance requirements for small entities. Regulatory fee payors, including small entities, will be required to pay the regulatory fees after such fees are adopted.

E. Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

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

38. The Commission has taken steps to minimize the economic impact on

small entities by adopting a de minimis threshold under the section 9(e)(2) exemption in the Communications Act. Section 9(e)(2) of the Communications Act permits the Commission to exempt a party from paying regulatory fees if ''in the judgment of the Commission, the cost of collecting a regulatory fee established under this section from a party would exceed the amount collected from such party . . . .'' The threshold applies only to filers of annual regulatory fees, not regulatory fees paid through multi-year filings. Currently, the de minimis threshold for annual regulatory fee payors is $1,000 or less for the fiscal year. In the *NPRM,* the Commission seeks comment on the feasibility of raising the de minimis threshold.

F. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

39. None.

VII. Ordering Clauses

40. Accordingly, *it is ordered* that, pursuant to sections 47 U.S.C. 4(i), 4(j), 9, 9A, and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 154(j), 159, 159A, and 303(r), this *NPRM is hereby adopted.*

Federal Communications Commission.

Marlene Dortch,

Secretary.

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The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available at *https://www.govinfo.gov*. Some laws may not yet be available.

H.R. 735/P.L. 117–155
To designate the facility of the United States Postal Service located at 502 East Cotati Avenue in Cotati, California, as the ''Arturo L. Ibleto Post Office Building''. (June 24, 2022; 136 Stat. 1306)

H.R. 767/P.L. 117–156
To designate the facility of the United States Postal Service located at 40 Fulton Street in Middletown, New York, as the ''Benjamin A. Gilman Post Office Building''. (June 24, 2022; 136 Stat. 1307)

H.R. 1444/P.L. 117–157
To designate the facility of the United States Postal Service located at 132 North Loudoun Street, Suite 1 in Winchester, Virginia, as the ''Patsy Cline Post Office''. (June 24, 2022; 136 Stat. 1308)

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