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Contents

Federal Register

Vol. 89, No. 97

Friday, May 17, 2024

Separate Parts In This Issue

Reader Aids

Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

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CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

5 CFR
2635 43686

14 CFR
71 43305
93 43309

Proposed Rules:
39 (4 documents) 43336, 43339, 43342, 43344
71 43347

21 CFR

Proposed Rules:
73 43349

26 CFR

Proposed Rules:
1 43349
301 43349

29 CFR
2520 43636
2550 (2 documents) 43636, 43675
2578 43636

31 CFR
560 43311

33 CFR
100 43314
165 (2 documents) 43316, 43318

Proposed Rules:
165 43350

34 CFR

Proposed Rules:
Ch. VI 43352

36 CFR
7 43319

40 CFR
174 43328
282 43322
372 43331

Proposed Rules:
52 (2 documents) 43357, 43359
282 43363

42 CFR

Proposed Rules:
512 43518

50 CFR

Proposed Rules:
648 43364

Rules and Regulations

Federal Register
Vol. 89, No. 97
Friday, May 17, 2024

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2023–1021; Airspace Docket No. 22–AWA–6]

RIN 2120–AA66

Establishment of Class C Airspace and Removal of Class D Airspace; Harrisburg International Airport, PA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class C airspace and removes Class D airspace at the Harrisburg International Airport (MDT), PA. The Class C airspace created is larger than the existing Class D airspace at MDT and is described as areas A through F. In addition, the non-regulatory Terminal Radar Service Area (TRSA) is removed. The FAA is taking this action to enhance the efficient management of air traffic operations and reduce the potential for midair collision in the MDT terminal area.

DATES: Effective date 0901 UTC, July 11, 2024. 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 7400.11 and publication of conforming amendments.

ADDRESSES: A copy of the NPRM, all comments received, this final rule, and all background material may be viewed online at *www.regulations.gov* using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at *www.federalregister.gov.*

FAA Order JO 7400.11H, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Brian Vidis, 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 terminal airspace as required to preserve the safe and efficient flow of air traffic in the Harrisburg, PA, area.

History

The FAA published a notice of proposed rulemaking for Docket No. FAA–2023–1021 in the **Federal Register** (88 FR 54503; August 11, 2023) proposing to establish Class C airspace area surrounding MDT. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. Four comments were received.

Discussion of Comments

The FAA received anonymous comments supporting the establishment of the Harrisburg Class C airspace. Discussion of the other comments follows.

One commenter supported the establishment of the Harrisburg Class C airspace. This comment also thanked the FAA for its efforts to ensure that the Class C rulemaking did not affect Capital City Airport (CXY), PA operations, notably the Runway 12/30 traffic pattern and CXY Instrument Landing System (ILS) runway 8 approach, for aircraft that do not meet Class C equipment requirements. This commenter also suggested revising the CXY Class E airspace descriptions in FAA Order JO 7400.11 due to an apparent error.

In response to the comment associated with operations at CXY, the FAA received neither comments nor proposals that would further restrict operations at CXY. Additionally, the FAA did not consider any amendment to the Class C airspace design as proposed in the NPRM. Further, the remainder of the comment is beyond the scope of this rulemaking, noting that the FAA proposed changes to the CXY Class D and Class E airspace via a separate action.[1]

The last comment was received from Boeing, which identified a possible typographical error in the geographic point ''lat. 40°14′12″ N, long. 077°56′05″ W'' listed in Area E of the Harrisburg Class C airspace description. The commenter indicated that this point would not create Area E as depicted in the graphic and believed that the geographic point should have been ''lat. 40°14′12″ N, long. 076°56′05″ W''. The FAA reviewed the geographic coordinates in the proposed description of Area E and found that the geographic point published as ''lat. 40°14′12″ N, long. 077°56′05″ W'' was in error and the correct geographic coordinates are ''lat. 40°14′12″ N, long. 076°56′05″ W''. The graphic in the NPRM used the correct geographic coordinates for Area E and correctly depicted the intended layout of the Harrisburg Class C airspace.

Differences From the NPRM

Subsequent to publication of the NPRM, a commenter pointed out a typographical error in a geographic coordinate in Area E of the Harrisburg Class C airspace description. In Area E, the geographic point published as ''lat. 40°14′12″ N, long. 077°56′05″ W'' was in error and the correct geographic coordinates are ''lat. 40°14′12″ N, long. 076°56′05″ W''. The geographic point in Area E is changed from ''lat. 40°14′12″

[1] *Amendment of Class D Airspace, Revocation of Class D Airspace, and Amendment of Class E Airspace, Harrisburg, PA,* (88 FR 54956; August 14, 2023).

N, long. 077°56′05″ W'' to ''lat. 40°14′12″ N, long. 076°56′05″ W''.

Additionally, the FAA identified three boundary points that must be added to Area D of the Harrisburg Class C airspace description. These three additional boundary points are necessary to ensure that the boundary of Area D aligns with the boundaries of adjacent Area C and Area E. Adding these boundary points does not modify the external boundary of the Class C airspace but rather ensures that the internal boundaries of the airspace are coincident. The three boundary points that are added to Area D are lat. 40°12′37″ N, long. 076°49′12″ W; lat. 40°14′13″ N, long. 076°53′23″ W; lat. 40°14′12″ N, long. 076°56′05″ W. This final rule corrects these errors.

Incorporation by Reference

Class C airspace designations are published in paragraph 4000 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11H, dated August 11, 2023, and effective September 15, 2023. FAA Order JO 7400.11H is publicly available as listed in the **ADDRESSES** section of this document. This amendment will be published in the next update to FAA Order JO 7400.11.

FAA Order JO 7400.11H 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 Class C airspace and removing the existing Class D airspace area at the Harrisburg International Airport (MDT), PA. The latitude/longitude coordinates for the MDT and CXY airport reference points (ARP) are updated to reflect the current Airport Master Records data. Also, the existing MDT TRSA is removed and replaced by the Class C airspace area. The FAA is taking this action to enhance the safe and efficient use of airspace and reduce the risk of midair collision in the MDT terminal area (see the attached chart).

The MDT Class C airspace area consists of six sub-areas identified by the letters A through F, described as follows:

Area A: Area A extends from the surface up to 4,400 feet mean sea level (MSL) within a 5 nautical mile (NM) radius of MDT, except for that portion described as Area E, below, and excluding that area within a 1.5 NM radius of CXY, northeast of the airport. Area A replaces the existing Class D airspace at MDT.

Area B: Area B extends from 1,600 feet MSL up to 4,400 feet MSL. It consists of that airspace within 3.5 miles either side of the 117° bearing from MDT, between the 5-mile and 10-mile radii from MDT.

Area C: Area C extends from 1,600 feet MSL up to 4,400 feet MSL. It is located northwest of MDT between the 5-mile and 10-mile radii of MDT and bounded on the south side by Area E. Area C overlies a portion of the CXY Class D airspace area.

Area D: Area D extends from 2,100 feet MSL up to 4,400 feet MSL. Area D is bounded as follows: on the northwest end by the 15-mile radius of MDT northwest of MDT; on the northeast side by a line extending from the intersection of the 15-mile radius of MDT and the MDT's 325° bearing, direct to the intersection of MDT's 089° bearing and the 15-mile radius of MDT southeast of MDT; and on the southwest side, by a line extending from lat. 40°01′45″ N, long. 076°40′43″ W, to lat. 40°05′32″ N, long. 076°50′21″ W, excluding the airspace contained in Areas A, B, C, E, and F. Area D's 2,100-foot floor creates a shelf in the vicinity of Donegal Springs Airpark (N71), allowing for operations beneath the Class C airspace.

Area E: Area E extends from 2,600 feet MSL up to 4,400 feet MSL south and west of CXY. Area E overlays part of the CXY Class D airspace area to the south and west of CXY. Area E allows aircraft to operate to and from CXY without the need for pilots to enter Class C airspace.

Area F: Area F extends from 2,600 feet MSL up to 4,400 feet MSL. The Area F floor creates a shelf below which pilots could fly instrument approaches to Lancaster Airport (LNS) runway 08, without having to enter Class C airspace.

Full descriptions of the MDT Class C subareas are listed in the amendments to part 71 below.

Regulatory Notices and Analyses

The FAA considers the impacts of regulatory actions under a variety of executive orders and other requirements. First, Executive Order 12866 and Executive Order 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify the costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96–39) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a 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 $183 million using the most current (2023) Implicit Price Deflator for the Gross Domestic Product. This portion of the preamble presents the FAA's analysis of the economic impacts of this rule.

In conducting these analyses, the FAA has determined that this rule: will have a minimal cost impact; is not a ''significant regulatory action'' as defined in section 3(f)(1) of Executive Order 12866 as amended by Executive Order 14094; will not have a significant economic impact on a substantial number of small entities; will not create unnecessary obstacles to the foreign commerce of the United States; and will not impose an unfunded mandate on State, local, or tribal governments, or the private sector.

This final rule amends 14 CFR part 71 by establishing Class C airspace and removing the existing Class D airspace area at the MDT, PA. In addition, the non-regulatory TRSA is removed. The rule will affect pilots desiring to fly at their current altitudes in and above the Class C airspace. The existing § 91.225 requires all planes to operate in Class C airspace to be equipped with Automatic Dependent Surveillance-Broadcast (ADS–B) Out equipment. Given that there is no Class C airspace at MDT, all planes that fly in and out of MDT must be equipped with ADS–B Out equipment in this airspace once the final rule goes into effect. However, the nearby Capital City Airport is about four miles from MDT and is not part of Class C airspace. The Capital City Airport could accommodate planes without ADS–B Out equipment.

This rule affects pilots because two-way radio communications must be established prior to entering Class C airspace. Pilots who wish to fly without communicating with air traffic control will need to modify their altitude and/or route of flight by either flying above the ceiling, below the shelves, or circumnavigating the Class C airspace. The impact of the final rule will only involve a minimal amount of time to communicate with the air traffic control (ATC). Therefore, the final rule does not have a significant impact on the

industry. The FAA is taking this action to reduce the risk of midair collisions and enhance the efficient management of air traffic operations in the Harrisburg terminal area.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (Pub. L. 96–354) (RFA) establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.'' The RFA covers a wide range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines it will, it must prepare a regulatory flexibility analysis as described in the RFA. However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify, and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

This final rule amends 14 CFR part 71 by establishing Class C airspace and removing the existing Class D airspace area at MDT. In addition, the non-regulatory TRSA is removed. The FAA is taking this action to reduce the risk of midair collisions and enhance the efficient management of air traffic operations at the MDT. The change affects general aviation operators using Class C airspace. The impact of the final rule will only involve a minimal amount of time for pilots to communicate with the ATC in Class C airspace. The objectives of these changes are to enhance safety and enable more efficient operations at the MDT without being burdensome to the industry. Therefore, as provided in section 605(b), the head of the FAA certifies that this rulemaking will not result in a significant economic impact on a substantial number of small entities.

International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for United States standards. The FAA has assessed the potential effect of this final rule and determined that it should improve safety and is consistent with the Trade Agreements Act. The FAA has assessed the potential impact of this final rule and determined that it will improve safety and is consistent with the Trade Agreements Act.

Unfunded Mandates Assessment

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a state, local, or tribal government or the private sector to incur direct costs without the Federal government having first provided the funds to pay those costs. The FAA determined that the final rule will not result in the expenditure of $183 million or more by State, local, or tribal governments, in the aggregate, or the private sector, in any year. This final rule does not contain such a mandate; therefore, the Act does not apply.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. The FAA has determined that this final rule has no new information collection requirement.

Environmental Review

The FAA has determined that this action of establishing Class C airspace and removing Class D airspace at the Harrisburg International Airport (MDT), PA 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.

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 7400.11H, Airspace Designations and Reporting Points, dated August 11, 2023, and effective September 15, 2023, is amended as follows:

Paragraph 4000 Class C Airspace.

* * * * *

AEA PA C Harrisburg, PA [New]

Harrisburg International Airport, PA
(Lat. 40°11′35″ N, long. 076°45′45″ W)
Capital City Airport, PA
(Lat. 40°13′02″ N, long. 076°51′05″ W)

Boundaries

Area A. That airspace extending upward from the surface to and including 4,400 feet MSL bounded by a line beginning at lat. 40°12′23″ N, long. 076°48′37″ W; thence direct to the intersection of the Capital City

Airport's 106° bearing and 1.5-mile radius, thence counterclockwise along the Capital City Airport's 1.5-mile radius to the Harrisburg International Airport's 5-mile radius, thence clockwise along the Harrisburg International Airport's 5-mile radius to the intersection of the 5-mile radius and a line bearing 191° from a point at lat. 40°12′23″ N, long. 076°48′37″ W; thence direct to the point of beginning.

Area B. That airspace extending upward from 1,600 feet MSL to and including 4,400 feet MSL extending from the Harrisburg International Airport's 5-mile radius, and within 3.5 miles each side of the Harrisburg International Airport's 117° bearing to the Harrisburg International Airport's 10-mile radius southeast of the Harrisburg International Airport.

Area C. That airspace extending upward from 1,600 feet MSL to and including 4,400 feet MSL bounded by a line beginning at the intersection of the Capital City Airport's 106° bearing and 1.5-mile radius direct to lat. 40°14′13″ N, long. 076°53′23″ W, direct to lat. 40°14′12″ N, long. 076°56′05″ W; thence direct to lat. 40°14′12″ N, long. 076°58′22″ W; thence clockwise along the Harrisburg International Airport's 10-mile radius to lat. 40°18′58″ N, long. 076°54′35″ W; thence direct to the Harrisburg International Airport's 341° bearing and the Harrisburg International Airport's 5-mile radius, thence counterclockwise along the Harrisburg International Airport's 5-mile radius to the intersection of the Capital City Airport's 1.5-mile radius, thence clockwise along the Capital City Airport's 1.5-mile radius to the point of beginning.

Area D. That airspace extending upward from 2,100 feet MSL to and including 4,400 feet MSL, within an area bounded by a line beginning at lat. 40°14′12″ N, long 076°58′22″ W; thence direct to lat. 40°14′11″ N, long. 077°05′03″ W; thence clockwise along the Harrisburg International Airport's 15-mile radius to the intersection of the Harrisburg International Airport's 325° bearing; thence direct to the intersection of Harrisburg International Airport's 089° bearing and the Harrisburg International Airport's 15-mile radius, thence clockwise along the airport's 15-mile radius to the intersection of the Harrisburg International Airport's 113° bearing; thence direct to lat. 40°01′45″ N, long. 076°40′43″ W; thence direct to lat. 40°05′32″ N, long. 076°50′21″ W; thence direct to lat. 40°12′23″ N, long. 076°48′37″ W; thence direct to lat. 40°12′37″ N, long. 076°49′12″ W; thence direct to lat. 40°14′13″ N, long. 076°53′23″ W; thence direct to lat. 40°14′12″ N, long. 076°56′05″ W; thence to the point of beginning; excluding that airspace contained in Areas A, B, and C.

Area E. That airspace extending upward from 2,600 feet MSL to and including 4,400 feet MSL bounded by a line beginning at lat. 40°12′23″ N, long. 076°48′37″ W; thence direct to lat. 40°05′32″ N, long. 076°50′21″ W; thence direct to the Harrisburg International Airport's 269° bearing and Harrisburg International Airport's 15-mile radius, thence clockwise along the Harrisburg International Airport's 15-mile radius to lat. 40°14′11″ N, long. 077°05′03″ W; thence direct to lat. 40°14′12″ N, long. 076°58′22″ W; thence direct to lat. 40°14′12″ N, long. 076°56′05″ W; thence direct to lat. 40°14′13″ N, long. 076°53′23″ W; thence direct to lat. 40°12′37″ N, long. 076°49′12″ W; thence direct to the point of beginning.

Area F. That airspace extending upward from 2,600 feet MSL to and including 4,400 feet MSL bounded by a line beginning at the intersection of the Harrisburg International Airport's 113° bearing and the airport's 15-mile radius; thence clockwise along the Harrisburg International Airport's 15-mile radius to the intersection of the airports 145° bearing and the airport's 15-mile radius; thence direct to lat. 40°01′45″ N, long. 076°40′43″ W; thence direct to the point of beginning.

* * * * *

Paragraph 5000 Class D Airspace

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AEA PA D Harrisburg International Airport, PA [Removed]

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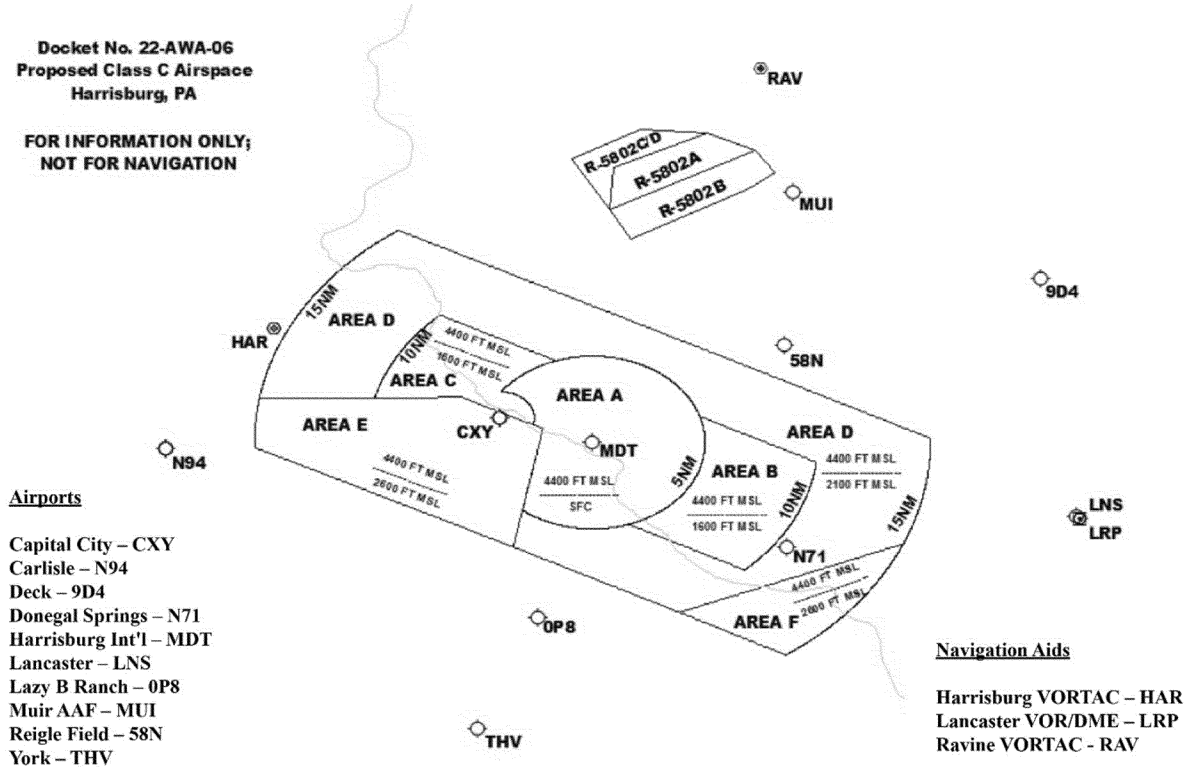

Issued in Washington, DC, on May 9, 2024.

Frank Lias,

Manager, Rules and Regulations Group.

[FR Doc. 2024–10612 Filed 5–16–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 93

Runway Closure-Related Scheduling Relief Concerning Operations at San Francisco International Airport, Newark Liberty International Airport, Chicago O'Hare International Airport, Los Angeles International Airport, and John F. Kennedy International Airport, January 15, 2024, Through July 15, 2024

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

ACTION: Notification of limited waiver of slot usage requirement and limited scheduling relief.

SUMMARY: This notification announces a limited, conditional policy for prioritizing returned operations at San Francisco International Airport (SFO) due to a construction-related runway closure at SFO for purposes of establishing a carrier's operational baseline in the next corresponding scheduling seasons. In addition, the FAA will provide similar limited, conditional relief at Newark Liberty International Airport (EWR), Chicago O'Hare International Airport (ORD), and Los Angeles International Airport (LAX) under the FAA's Level 2 schedule facilitation process as well as a limited, conditional waiver of minimum usage requirements at John F. Kennedy International Airport (JFK) for impacted flights between SFO and the listed airports.

DATES: The limited waiver of slot usage requirement and limited scheduling relief in this notification are effective May 17, 2024, and applicable from January 15, 2024, through July 15, 2024.

ADDRESSES: Requests may be submitted by mail to the Slot Administration Office, System Operations Services, AJR–0, Room 300W, 800 Independence Avenue SW, Washington, DC 20591, or by email to: *7-awa-slotadmin@faa.gov.*

FOR FURTHER INFORMATION CONTACT: For questions concerning this notification contact: Al Meilus, Capacity and Slot Analysis, FAA ATO System Operations Services, AJR–G5, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone 202–267–2822; email *al.meilus@faa.gov.*

SUPPLEMENTARY INFORMATION: The relief provided enables carriers to return operations at SFO during the construction periods of the Winter 2023/2024 and Summer 2024 scheduling seasons without unduly impacting schedules in subsequent seasons.[1] Reducing operations will help prevent delays, optimize the efficient use of the airport's available resources, and deliver passengers to their destinations more reliably and on time.

Background

SFO is rehabilitating one of its four runways, Runway 10R/28L, to maintain runway operability; to construct a new taxiway to improve operational efficiency; and to realign an existing taxiway to rectify deficiencies with current SFO geometry. Runway 10R/28L is one of two parallel runways oriented in the east-west direction and is used as a primary arrival runway and a secondary departure runway. The construction will cause the continuous closure of Runway 10R/28L from January 15, 2024, through June 30, 2024.

On October 26, 2023, the FAA held an initial meeting with all the carriers that have scheduled operations at SFO. The FAA gave a presentation on the expected impact of the construction project on operations at SFO and recommended a reduction in operations to alleviate potential delays and cancellations. SFO initially planned for the project to occur in two phases: Phase 1 planned for January 16, 2024, through May 28, 2024; and Phase 2 planned for September 3, 2024, through October 25, 2024.

On December 14, 2023, the FAA and SFO held a joint meeting with all the carriers that have scheduled operations at SFO. SFO announced that Phase 2 had been rescheduled to begin on May 29, 2024, and end on June 30, 2024. This change allows the construction to be condensed into one continuous block of time from January 15, 2024, through June 30, 2024.

At both meetings, the FAA requested that carriers voluntarily return operations. Carriers were asked to make initial returns by November 2, 2023, for the affected portion of the winter scheduling season; and by January 11, 2024, for the affected portion of the summer 2024 scheduling season. The FAA subsequently determined that relief granted for the construction period should extend beyond the construction period by an additional 15 days to accommodate carriers resuming normal scheduled operations.

The FAA has designated SFO, EWR, ORD, and LAX as Level 2 airports under the Worldwide Slot Guidelines (WSG).[2] The FAA does not allocate slots, apply historic precedence, or impose minimum usage requirements at SFO. Level 2 schedule facilitation depends upon close and continuous discussions and voluntary agreement between airlines and the FAA to reduce congestion. At Level 2 airports, the FAA generally provides priority consideration for flights approved by the FAA and operated by the carrier in those approved times in the prior scheduling season when the FAA reviews proposed flights for facilitation in the next corresponding scheduling season. Only those flights that were actually operated as approved in the prior scheduling season would generally receive priority for the next corresponding scheduling season. However, the FAA notes that the usual Level 2 processes include flexibility for the facilitator to prioritize planned flights, which are canceled in advance or on the day of the scheduled operation due to operational impacts that are beyond the control of the carrier.

At JFK, each slot must be used a minimum of 80 percent of the time.[3] Slot usage at JFK is calculated seasonally. Slots not meeting the minimum usage requirement will not receive historic status for the following equivalent scheduling season.[4] The FAA may waive the 80 percent minimum usage requirement if a highly unusual and unpredictable condition beyond the control of the slot-holding air carrier affects carrier operations for

[1] For the purposes of this notification, a ''returned operation'' is any planned operation included in the initially approved schedules that a carrier moved or will not operate due to the effort to reach the targeted reduced schedule throughout the construction period at SFO. If a carrier elected to move an operation, the operation was rescheduled outside of peak demand hours or hours adjacent to peak demand as detailed in this notification.

[2] The FAA generally applies the WSG to the extent there is no conflict with U.S. law or regulation. The FAA recognizes the WSG has been replaced by the Worldwide Airports Slot Guidelines (WASG) edition 1, effective June 1, 2020, and subsequently WASG edition 2, effective July 1, 2022. The WASG is published jointly by Airports Council International-World, IATA, and the Worldwide Airport Coordinators Group (WWACG). While the FAA is considering whether to implement certain changes to the Guidelines in the United States, it will continue to apply WSG edition 9.

[3] Operating Limitations at John F. Kennedy International Airport, 87 FR 65161 at 65162 (Oct. 28, 2022); Operating Limitations at New York LaGuardia Airport, 87 FR 65159 at 65160 (Oct. 28, 2022); 14 CFR 93.227(a).

[4] Operating Limitations at John F. Kennedy International Airport, 87 FR 65161 at 65162 (Oct. 28, 2022).

a period of five consecutive days or more at JFK.[5]

FAA Analysis

Due to the daily volume of flights arriving and departing SFO, the closure of Runway 10R/28L is expected to significantly affect carriers' ability to operate reliably and on time. Absent increased scheduling flexibility during the construction period, the FAA anticipates a high likelihood of congestion, delays, and cancellations at SFO, with related impact at EWR, ORD, LAX, and JFK. The runway closure is expected to impact carrier operations at SFO especially in the the peak demand hours of 0900, 1200, 1500, 1700, 1800, 2000, and 2100 hours.

The FAA modeled two scenarios of the expected delays at SFO for Phase 1 and Phase 2 respectively: one scenario without any mitigation measures, and one scenario with arrival limit mitigation measures in place. The mitigation measures incorporate Air Traffic Control (ATC) data used to assess capacity at SFO throughout the construction period. These mitigation measures align with the number of operations that ATC finds to be sustainable during the runway closure, while accounting for the differing arrival demand profiles in Phase 1 and Phase 2.

Phase 1 of the construction requires a total closure of Runway 10R/28L, with Taxiways D and T partially affected. As such, for the scenario without any mitigation measures, the FAA estimates approximately 78% of total arrivals would be delayed by an average of 49 minutes per arrival. These arrival delays would be unrecoverable throughout the day.

The FAA then modeled a scenario that limited the arrivals to no more than 30 per hour throughout the day, except for the 0900, 1200, 1500, 1700, 1800, 2000, and 2100 hours where the arrival limit is increased to no more than 35 per hour. This is because Phase 1 arrival demand varies by hour, with peak arrival demand exceeding 35 per hour, and off-peak arrival demand decreasing in some hours to under 25 arrivals per hour. Given that the capacity of the airport is limited to 30 arrivals per hour on average, the target arrival limits are set by hour to accommodate variable hourly arrival demand, with an ability to recover in adjacent hours. With this mitigation measure in place, the FAA estimates that approximately 52% of total arrivals will experience an average delay of about 21 minutes per arrival.

Phase 2 of the construction requires the total closure of Runway 10R/28L and Taxiways D and T. As such, for the scenario without any mitigation measures, the FAA estimates approximately 90% of total arrivals would be delayed by an average of 87.6 minutes per arrival. The consequences of arrival delays of over two hours would result in 89 arrival cancellations per day.[6] These arrival delays are expected to be unrecoverable throughout the day.

The FAA also modeled a scenario that limited the arrivals to no more than 27 per hour throughout the day. This is because for Phase 2 the hourly arrival demand exceeds the airport's arrival capacity in every hour; therefore, the target scheduling limit is set to the airport's arrival capacity for every hour throughout the day. With this mitigation measure in place, the FAA estimates that approximately 24% of total arrivals will experience an average delay of approximately 10.4 minutes per arrival.

After assessing these scenarios, the FAA determined that the mitigation measures for both Phase 1 and Phase 2 will balance efficient and timely operations at SFO during the construction period and limit the impact on carrier's scheduled operations for the convenience of the flying public. Although the potential for significant delays may still occur on late evenings during high-traffic days, the majority of operating hours will be manageable throughout the day during the construction period.

Decision

The FAA has determined that the construction and resulting runway closure at SFO warrants limited, conditional schedule relief because the impacts to operations are beyond the carriers' control and will persist for several months during 2024.

For Phase 1, the FAA requests that carriers reduce operations in the 0900, 1200, 1500, 1700, 1800, 2000, and 2100 hours to no more than 35 arrivals in each of these hours, without moving operations into the adjacent hours. The adjacent hours are heavily subscribed with departures, limiting the ability to move arrivals from peak hours into the adjacent hours. Because the current scheduled arrival demand at SFO for each of those hours is well above 35 arrivals,[7] doing so would result in a reduction of about 55 to 60 operations on peak days during the construction period, depending on the day/week/month.

For Phase 2, the FAA requests that carriers reduce operations to no more than 27 arrivals per hour, without moving operations into the adjacent hours. Because the current scheduled arrival demand at SFO for each of those hours is well above 27 arrivals, doing so would result in a reduction of about 140 operations on peak days during the construction period, depending on the day or week or month.

The FAA is not limiting the relief to specific hours in order to provide some degree of flexibility to carriers to allow them to balance schedules and slot pairs. The FAA will continue to work with carriers on retiming and schedule adjustment options throughout the construction period as needed.

This relief is effective from January 15, 2024, through July 15, 2024. This provides some time before and after the currently planned runway closure dates to accommodate potential changes to the construction schedule, and provide carriers that may need some relief on either side of the current anticipated construction dates to phase in or phase out current operations.

In addition, the FAA is extending a limited, conditional waiver from minimum usage requirements at JFK for departure slots for nonstop service to SFO, and providing similar relief at EWR, LAX, and ORD under the Level 2 process for approved schedules associated with a SFO departures for nonstop service to these U.S. airports. Carriers may also choose to use those slots at JFK and or the approved runway times at EWR, LAX, and ORD for operations to airports other than SFO.

For the duration of the construction period, the FAA will recognize priority of approved schedules or the historical precedence of related slots, subject to the following conditions.

1. Slots or approved schedules for initial use in the Winter 2023/2024 scheduling season are not eligible for relief. Slots or schedules approved for initial use in the Summer 2024 scheduling season are not eligible for relief.

2. Slots granted historic precedence for subsequent seasons based on this relief are not eligible for transfer if the slot holder ceases all operations at the airport.

[5] Operating Limitations at John F. Kennedy International Airport, 87 FR 65161 at 65163 (Oct. 28, 2022); Operating Limitations at New York LaGuardia Airport, 87 FR 65159 at 65160 (Oct. 28, 2022); 14 CFR 93.227(j).

[6] The FAA's delay model assumes that when estimated delay becomes greater than 2 hours, an airline will cancel the operation.

[7] 0900 hour has an arrival demand of 52. 1500 hour has an arrival demand of 39. 2100 hour has an arrival demand of 42.

Issued in Washington, DC, on May 2, 2024.

Alyce Hood-Fleming,

Vice President, System Operations Services.

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DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 560

Iranian Transactions and Sanctions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is adopting a final rule amending the Iranian Transactions and Sanctions Regulations (ITSR) to incorporate a general license that was previously published on OFAC's website. In particular, the rule incorporates, with amendments, a general license relating to the export, reexport, and provision of certain services, software, and hardware incident to communications over the internet. This amendment also makes additional conforming changes.

DATES: This rule is effective May 17, 2024.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website *https://ofac.treasury.gov.*

Background

On October 22, 2012, OFAC issued a final rule that amended the former Iranian Transactions Regulations, 31 CFR part 560 (ITR), and reissued them in their entirety as the Iranian Transactions and Sanctions Regulations (ITSR or ''the Regulations'') (77 FR 64664, October 22, 2012). Since then, OFAC has amended the Regulations on several occasions. As set forth in more detail below, OFAC is now amending the Regulations to incorporate, with certain amendments, a general license that previously was published on OFAC's website and to make additional conforming changes.

Services, Software, and Hardware Incident to Personal Communications. On March 10, 2010, in order to foster and support the free flow of information to individual Iranian citizens, OFAC issued a final rule amending the ITR to add a general license in § 560.540 authorizing the exportation of certain services and software incident to the exchange of personal communications over the internet, provided that, among other things, such services and software were publicly available at no cost to the user (75 FR 10997, March 10, 2010). The authorization under § 560.540 was preserved in the ITSR, as reissued in October 2012 (77 FR 64664).

On May 30, 2013, OFAC, in consultation with the Departments of State and Commerce, issued General License (GL) D under the Regulations. GL D was made available on OFAC's website and the **Federal Register** (78 FR 43278, July 19, 2013). GL D authorized the exportation or reexportation, directly or indirectly, from the United States or by U.S. persons, wherever located, to persons in Iran of additional services, software, and hardware incident to personal communications, including fee-based versions of the software and services authorized in § 560.540, subject to certain conditions. GL D also contained an Annex that listed items authorized for export or reexport to Iran that had been determined to be incident to personal communications.

On February 7, 2014, OFAC issued GL D–1, which replaced and superseded GL D in its entirety. GL D–1 was made available on OFAC's website and the **Federal Register** (79 FR 13736, March 11, 2014). GL D–1 clarified certain aspects of GL D and added new authorizations relating to the provision to Iran and importation from Iran of certain hardware, software, and services incident to personal communications. GL D–1 also updated the Annex from GL D with minor technical amendments. On September 23, 2022, OFAC issued GL D–2, which replaced and superseded GL D–1 in its entirety. GL D–2 was made available on OFAC's website and in the **Federal Register** (87 FR 62003, October 13, 2022). GL D–2 updated and clarified GL D–1 by, among other things: removing the ''personal'' qualifier from the authorization for software and services incident to ''personal communication''; providing additional examples of modern types of software and services that are incident to the exchange of communications, including social media platforms, collaboration platforms, video conferencing, e-gaming, e-learning platforms, automated translation, web maps, and user authentication services; explicitly authorizing cloud-based services and software in support of the foregoing software or services or of any other transaction that is authorized pursuant to the Regulations; clarifying the restrictions on the exportation of web-hosting services or domain name registration services; and expanding the specific licensing policy set forth in GL D–1. GL D–2 maintained the Annex as updated by GL D–1.

OFAC, in consultation with the Departments of State and Commerce, is now amending the Regulations to incorporate the provisions of GL D–2 and certain additional amendments into the existing authorization at § 560.540. First, OFAC is amending § 560.540(a) to incorporate paragraphs (a)(1) and (2) of GL D–2, which authorize the exportation or reexportation to Iran of certain no-cost or fee-based services and software that are incident to, and software that enables services incident to, the exchange of communications over the internet, as well as cloud-based services in support of the foregoing services or of any other transactions authorized or exempt under the Regulations, subject to certain conditions. New § 560.540(a)(3) incorporates paragraph (a)(3) of GL D–2, which authorizes the exportation, reexportation, or provision of certain software, hardware, and related services not authorized by § 560.540(a)(1) or (2). OFAC is also publishing in the **Federal Register** a list of the services, software, and hardware authorized by new § 560.540(a)(3) (the ''List of Services, Software, and Hardware Incident to Communications under 31 CFR 560.540''), which includes the items previously listed in the Annex to GL D–2. However, concurrent with this rule, OFAC is publishing an update, effective 30 days after publication of this rule, that would amend the ''List of Services, Software, and Hardware Incident to Communications under 31 CFR 560.540'' to limit the computing power of laptops, tablets, and personal computing devices that are authorized for exportation or reexportation to Iran under category (5) of ''List of Services, Software, and Hardware Incident to Communications under 31 CFR 560.540'', in order to address concerns about the use of multiple, connected computing devices with increased computing powers to create high-powered computers. The updated ''List of Services, Software, and Hardware Incident to Communications under 31 CFR 560.540'' is being published separately in the **Federal Register**. New § 560.540(a)(4) through (6) incorporate

paragraphs (a)(4) through (6) of GL D–2, which authorize: the exportation or reexportation of certain internet connectivity services and the provision, sale, or lease of telecommunications facilities incident to communications; the importation into the United States or a third country of hardware and software previously exported to Iran; and the exportation and reexportation of certain publicly available, no-cost services and software to the Government of Iran, respectively.

OFAC is also expanding § 560.540 in two ways to address repair and replacement issues with respect to items exported pursuant to the ITSR. First, OFAC is revising the authorization at paragraph (a)(5) of GL D–2 and incorporating the revised text into § 560.540(a)(5), to authorize transactions for the importation of hardware or software into third countries, in addition to the United States, provided that the items were previously exported to Iran pursuant to an authorization issued pursuant to the ITSR. Second, OFAC is adding a new § 560.540(a)(7) to authorize the exportation or reexportation, of certain services conducted outside Iran to install, repair, or replace hardware or software authorized for exportation, reexportation, or provision to Iran by paragraph (a)(2) or (3) of that section. The new § 560.540(a)(7) authorizes such services only when the service provider is located outside Iran and does not authorize the service providers to engage in such services while in Iran.

This final rule also revises § 560.540(b) to incorporate paragraph (b) of GL D–2, which includes restrictions on transactions authorized by § 560.540(a), with slight revisions. Section 560.540(b)(3) refines and clarifies the restrictions of paragraph (b)(4) of GL D–2 related to the provision of web-hosting services or of domain name registration services in Iran. Specifically, newly revised § 560.540(b)(3) excludes from authorization the exportation or reexportation of web-hosting services for websites of commercial entities located in Iran or of domain name registration services for or on behalf of the Government of Iran or another person whose property and interests in property are blocked pursuant to § 560.211.

OFAC is revising § 560.540(c) to incorporate paragraph (c) of GL D–2 into § 560.540(c)(1), which provides that U.S. depository institutions and U.S. registered brokers or dealers in securities may process transfers of funds in furtherance of an underlying transaction authorized by § 560.540(a), provided the transfer does not involve debiting or crediting an Iranian account. U.S. depository institutions and U.S. registered brokers or dealers in securities may also continue to process transfers of funds that are ordinarily incident and necessary to authorized transactions pursuant to § 560.516.

OFAC is also adding a new § 560.540(d) to incorporate the specific licensing policy set forth in paragraph (d) of GL D–2, which expands upon the specific licensing policy previously set forth in § 560.540(c). The new § 560.540(d) sets forth a case-by-case licensing policy for additional activities that support internet freedom in Iran. OFAC is not incorporating certain notes and a provision in GL D–2 that are duplicative of prohibitions that continue to apply independently from the Regulations and therefore are unnecessary to include. Finally, OFAC is adding an explanatory note referring to this general license in §§ 560.418, 560.508, and 560.519. Upon publication of this final rule, OFAC will archive GL D–2 on its website. GLs D, D–1, and D–2 will continue to be available in the **Federal Register**: GL D was published in the **Federal Register** on July 19, 2013 (78 FR 43278, July 19, 2013); GL D–1 was published in the **Federal Register** on March 11, 2014 (79 FR 13736, March 11, 2014); and GL D–2 was published in the **Federal Register** on October 13, 2022 (87 FR 62003, October 13, 2022).

Public Participation

Because the Regulations involve a foreign affairs function, the provisions of Executive Order (E.O.) 12866 of September 30, 1993, ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993), as amended, and the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

Paperwork Reduction Act

The collections of information related to the Regulations are contained in 31 CFR part 501 (the ''Reporting, Procedures and Penalties Regulations''). Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), those collections of information have been approved by the Office of Management and Budget under control number 1505–0164. 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.

List of Subjects in 31 CFR Part 560

Administrative practice and procedure, Banks, banking, Blocking of assets, Communications, Credit, Foreign trade, Iran, Nonprofit organizations, Penalties, Reporting and recordkeeping requirements, Sanctions, Securities, Services.

For the reasons set forth in the preamble, OFAC amends 31 CFR part 560 as follows:

PART 560—IRANIAN TRANSACTIONS AND SANCTIONS REGULATIONS

■ 1. The authority citation for part 560 continues to read as follows:

Authority: 3 U.S.C. 301; 18 U.S.C. 2339B, 2332d; 22 U.S.C. 2349aa-9, 7201–7211, 8501–8551, 8701–8795; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890, as amended (28 U.S.C. 2461 note); E.O. 12613, 52 FR 41940, 3 CFR, 1987 Comp., p. 256; E.O. 12957, 60 FR 14615, 3 CFR, 1995 Comp., p. 332; E.O. 12959, 60 FR 24757, 3 CFR, 1995 Comp., p. 356; E.O. 13059, 62 FR 44531, 3 CFR, 1997 Comp., p. 217; E.O. 13599, 77 FR 6659, 3 CFR, 2012 Comp., p. 215; E.O. 13846, 83 FR 38939, 3 CFR, 2018 Comp., p. 854.

Subpart D—Interpretations

■ 2. Amend § 560.418 by adding note 3 to the section to read as follows:

§ 560.418 Release of technology or software in the United States or a third country.

* * * * *

Note 3 to § 560.418: *See* § 560.540 for a general license authorizing the exportation, reexportation, or provision to Iran of certain services, software, and hardware incident to the exchange of communications.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

■ 3. Amend § 560.508 by adding note 1 to paragraph (a) to read as follows:

§ 560.508 Telecommunications and mail transactions authorized.

(a) * * *

Note 1 to paragraph (a): *See* § 560.540 for a general license authorizing the exportation, reexportation, or provision to Iran of certain services, software, and hardware incident to the exchange of communications.

* * * * *

■ 4. Amend § 560.519 by revising the headings of the note to paragraph (c)(1) and the note to the section and adding note 3 to the section to read as follows:

§ 560.519 Journalistic activities and establishment of news bureaus in Iran.

* * * * *

Note 1 to paragraph (c)(1): * * *

* * * * *

Note 2 to § 560.519: * * *

Note 3 to § 560.519: *See* § 560.540 for a general license authorizing the exportation, reexportation, or provision to Iran of certain services, software, and hardware incident to the exchange of communications.

■ 5. Revise § 560.540 to read as follows:

§ 560.540 Certain services, software, and hardware incident to communications.

(a) To the extent that such transactions are not exempt from the prohibitions of this part, and subject to the restrictions set forth in paragraph (b) of this section, the following transactions are authorized:

(1) *Services.* The exportation or reexportation, directly or indirectly, from the United States or by a U.S. person, wherever located, to Iran of services incident to the exchange of communications over the internet, such as instant messaging, chat and email, social networking, sharing of photos and movies, web browsing, blogging, social media platforms, collaboration platforms, video conferencing, e-gaming, e-learning platforms, automated translation, web maps, and user authentication services, as well as cloud-based services in support of the foregoing or of any other transaction authorized or exempt under this part.

(2) *Software*—(i) *Software subject to or excluded from the EAR.* The exportation, reexportation, or provision, directly or indirectly, to Iran of software subject to the Export Administration Regulations, 15 CFR parts 730 through 774 (EAR), pursuant to 15 CFR 734.3(a), that is incident to, or enables services incident to, the exchange of communications over the internet, such as instant messaging, chat and email, social networking, sharing of photos and movies, web browsing, blogging, social media platforms, collaboration platforms, video conferencing, e-gaming, e-learning platforms, automated translation, web maps, and user authentication services, as well as cloud-based services in support of the foregoing or of any other transaction authorized or exempt under this part, provided that such software is designated EAR99, excluded from the EAR because it is described under 15 CFR 734.3(b)(3), or classified by the U.S. Department of Commerce on the Commerce Control List, 15 CFR part 774, supplement No. 1 (CCL), under export control classification number (ECCN) 5D992.c.

(ii) *Software that is not subject to the EAR because it is of foreign origin and is located outside the United States.* The exportation, reexportation, or provision, directly or indirectly, by a U.S. person, wherever located, to Iran of software that is not subject to the EAR because it is of foreign origin and is located outside the United States, that is incident to, or enables services incident to, the exchange of communications over the internet, such as instant messaging, chat and email, social networking, sharing of photos and movies, web browsing, blogging, social media platforms, collaboration platforms, video conferencing, e-gaming, e-learning platforms, automated translation, web maps, and user authentication services, as well as cloud-based services in support of the foregoing or of any other transaction authorized or exempt under this part, provided that such software would be designated EAR99 if it were located in the United States or would meet the criteria for classification under ECCN 5D992.c if it were subject to the EAR.

(3) *Additional software, hardware, and related services.* To the extent not authorized by paragraph (a)(1) or (2) of this section, the exportation, reexportation, or provision, directly or indirectly, to Iran of certain software and hardware incident to communications, as well as related services, as follows:

(i) In the case of hardware and software subject to the EAR, the items specified in the ''List of Services, Software, and Hardware Incident to Communications under 31 CFR 560.540'', which is maintained on OFAC's website (*https://ofac.treasury.gov*) on the Iran Sanctions page;

(ii) In the case of hardware and software that is not subject to the EAR because it is of foreign origin and is located outside the United States that is exported, reexported, or provided, directly or indirectly, by a U.S. person, wherever located, hardware and software that is of a type described in the ''List of Services, Software, and Hardware Incident to Communications under 31 CFR 560.540'', provided that the item would be designated EAR99 if it were located in the United States or would meet the criteria for classification under the relevant ECCN specified in the ''List of Services, Software, and Hardware Incident to Communications under 31 CFR 560.540'' if it were subject to the EAR; and

(iii) In the case of software not subject to the EAR because it is described in 15 CFR 734.3(b)(3) that is exported, reexported, or provided, directly or indirectly, from the United States or by a U.S. person, wherever located, software that is of a type described in the ''List of Services, Software, and Hardware Incident to Communications under 31 CFR 560.540''.

Note 1 to paragraphs (a)(2) and (3): The authorizations in paragraphs (a)(2) and (3) of this section include the exportation, reexportation, or provision, directly or indirectly, to Iran of authorized hardware and software by an individual leaving the United States for Iran.

(4) *Internet connectivity services and telecommunications capacity.* The exportation or reexportation, directly or indirectly, from the United States or by a U.S. person, wherever located, to Iran of non-commercial-grade internet connectivity services, to include cloud-based services, and the provision, sale, or leasing of capacity on telecommunications transmission facilities (such as satellite or terrestrial network connectivity) incident to communications.

Note 2 to paragraph (a)(4): *See* § 560.508 for authorizations relating to transactions with respect to the receipt and transmission of telecommunications involving Iran.

(5) *Importation into the United States or a third country of hardware and software previously exported to Iran.* The importation into the United States or a third country of hardware and software authorized for exportation, reexportation, or provision to Iran under paragraph (a)(2) or (3) of this section, provided that the hardware or software was previously exported, reexported, or provided to Iran under an authorization issued pursuant to this part.

Note 3 to paragraph (a)(5): *See* § 560.306 for definitions of the terms *goods of Iranian origin* and *Iranian-origin goods,* which do not include goods that have been previously exported or reexported to Iran under an authorization issued pursuant to this part and which have subsequently been exported from and are located outside of Iran.

(6) *Publicly available, no cost services and software to the Government of Iran*—(i) *Services.* The exportation or reexportation, directly or indirectly, from the United States or by a U.S. person, wherever located, to the Government of Iran, as defined in § 560.304, of services described in paragraph (a)(1) of this section or categories (6) through (11) of the ''List of Services, Software, and Hardware Incident to Communications under 31 CFR 560.540'', provided that such services are publicly available at no cost to the user.

(ii) *Software.* The exportation, reexportation, or provision, directly or indirectly, to the Government of Iran of software described in paragraph (a)(2) or (3) of this section or categories (6) through (11) of the ''List of Services,

Software, and Hardware Incident to Communications under 31 CFR 560.540'', provided that such software is publicly available at no cost to the user.

(7) *Services conducted outside Iran to install, repair, or replace.* The exportation or reexportation, directly or indirectly, from the United States or by a U.S. person, wherever located, to Iran of services conducted outside Iran to install, repair, or replace hardware or software authorized for exportation, reexportation, or provision to Iran pursuant to paragraph (a)(2) or (3) of this section.

Note 4 to paragraph (a): In paragraph (a)(6) of this section, the term ''publicly available'' refers generally to software that is widely available to the public. Paragraph (a)(3)(iii) of this section refers to software that is described in 15 CFR 734.3(b)(3), which defines ''publicly available'' software for purposes of the EAR. The scope of the term ''publicly available'' in paragraph (a)(6) of this section thus differs from the scope of the Department of Commerce's regulation at 15 CFR 734.3(b)(3) as referenced in paragraph (a)(3)(iii) of this section.

(b) This section does not authorize:

(1) The exportation, reexportation, or provision, directly or indirectly, of the services, software, or hardware specified in paragraph (a) of this section with knowledge or reason to know that such services, software, or hardware are intended for the Government of Iran, except for services or software specified in paragraph (a)(6) of this section, or for any person blocked pursuant to this part other than the Government of Iran.

(2) The exportation or reexportation, directly or indirectly, of commercial-grade internet connectivity services or telecommunications transmission facilities (such as dedicated satellite links or dedicated lines that include quality of service guarantees).

(3) The exportation or reexportation, directly or indirectly, of web-hosting services that are for websites of commercial entities located in Iran or of domain name registration services for or on behalf of the Government of Iran, as defined in § 560.304, or any other person whose property and interests in property are blocked pursuant to § 560.211.

(4) Any transaction by a U.S.-owned or -controlled foreign entity otherwise prohibited by § 560.215 if the transaction would be prohibited by any other part of chapter V if engaged in by a U.S. person or in the United States.

(5) Any action or activity involving any item (including information) subject to the EAR that is prohibited by, or otherwise requires a license under, part 744 of the EAR or participation in any transaction involving a person whose export privileges have been denied pursuant to part 764 or 766 of the EAR, without authorization from the Department of Commerce.

(c) Transfers of funds from Iran or for or on behalf of a person in Iran in furtherance of an underlying transaction authorized by paragraph (a) of this section may be processed by U.S. depository institutions and U.S. registered brokers or dealers in securities provided they are consistent with § 560.516.

(d) Specific licenses may be issued on a case-by-case basis for the exportation, reexportation, or provision of services, software, or hardware incident to communications not specified in paragraph (a) of this section, including in the ''List of Services, Software, and Hardware Incident to Communications under 31 CFR 560.540'', or other activities to support internet freedom in Iran, including development and hosting of anti-surveillance software by Iranian developers.

Bradley T. Smith,

Director, Office of Foreign Assets Control.

[FR Doc. 2024–10721 Filed 5–16–24; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[USCG–2024–0345]

RIN 1625–AA08

Special Local Regulation; York River, Yorktown, VA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary special local regulation for a portion of the navigable waters in the York River, in Yorktown, VA. The special local regulation is needed to protect personnel and vessels during the York River Workboat Races. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector Virginia.

DATES: This rule is effective from 11 a.m. until 3 p.m. on June 2, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2024–0345 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 about this rule, call or email LCDR Ashley Holm, Chief, Waterways Management Division, Sector Virginia, U.S. Coast Guard; telephone 757–668–5580, email *Ashley.E.Holm@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port, Sector Virginia
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 sponsor of the ''Yorktown Workboat Races,'' a high-speed boat race to be held at the Yorktown waterfront, has applied for a permit to conduct that event on June 2, 2024, as required by 33 CFR 100.15. After the approval of such a permit, the Captain of the Port, Sector Virginia (COTP) is authorized to promulgate such ''special local regulations'' as he or she deems necessary to ensure the safety of life on the navigable waters immediately prior to, during, and immediately after the event. *See* 33 CFR 100.35(a). This temporary rule embodies the special local regulations the COTP deems necessary for this event.

The Coast Guard is issuing this temporary rule under authority in 5 U.S.C. 553(b)(B). This statutory 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.'' The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable to publish an NPRM, provide a comment period, consider any comments submitted, and publish a final regulation by June 2, 2024, when the rule must be in effect to ensure the safety of life on the navigable waters during the Workboat Race scheduled to take place then.

In addition, the Coast Guard finds that good cause exists under 5 U.S.C. 553(d)(3) for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date would be contrary to the public interest, as it is in the public interest to have the rule in effect on June 2nd to ensure the safety of event spectators, and those in support craft and other vessels transiting the navigable waters

adjacent to the event. As noted below, advance notifications will be made to affected users of the waterway via Broadcast Notice to Mariners and Local Notice to Mariners.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The COTP has determined that potential hazards associated with a high-speed boat race on June 2, 2024, will be a safety concern for anyone within the race area. This rule is needed to protect personnel and vessels in the navigable waters within the special local regulation during the event.

IV. Discussion of the Rule

This rule establishes a special local regulation from 11 a.m. until 3 p.m. on June 2, 2024. The special local regulation will cover all navigable waters within the following latitude and longitude positions: 37°14′21.6″ N, 76°30′27.2″ W; 37°14′23.5″ N, 76°30′25.6″ W; 37°14′10.4″ N, 76°30′11.2″ W; 37°14′13.3″ N, 76°30′08.0″ W. The duration of the zone is intended to protect personnel and vessels in these navigable waters during a high-speed boat race. No vessel or person will be permitted to enter the area subject to this special local regulation without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, duration, and time-of-day of the special local regulation. Vessel traffic will be able to safely transit around this special local regulation which would impact a small, designated area of the York River for four hours on a Sunday when vessel traffic is normally low. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

In the spirit of 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 special local regulation lasting only 4 hours that will prohibit entry within the following latitude and longitude positions: 37°14′21.6″ N, 76°30′27.2″ W; 37°14′23.5″ N, 76°30′25.6″ W; 37°14′10.4″ N, 76°30′11.2″ W; 37°14′13.3″ N, 76°30′08.0″ W. It is categorically excluded from further review under paragraph L61 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 100

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 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

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

Authority: 46 U.S.C. 70041; 33 CFR 1.05–1.

■ 2. Add § 100.T599–0345 to read as follows:

§ 100.T599–0345 Special Local Regulation; York River, Yorktown, VA

(a) *Regulated area[s].* The regulations in this section apply to the following area: All waters of York River, from surface to bottom, encompassed by a line connecting the following points: 37°14′21.6″ N, 76°30′27.2″ W; 37°14′23.5″ N, 76°30′25.6″ W; 37°14′10.4″ N, 76°30′11.2″ W; 37°14′13.3″ N, 76°30′08.0″ W. These coordinates are based on WGS84.

(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 Sector Virginia (COTP) in the enforcement of the regulations in this section.

Non-Participant means any person or and vessel not registered with the event sponsor as a participant in the race.

(c) *Regulations.* (1) All non-participants are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area described in paragraph (a) of this section unless authorized by the COTP or their designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by VHF–FM Channel 16. Those in the regulated area must comply with all lawful orders or directions given to them by the COTP or the designated representative.

(3) The COTP will provide notice of the regulated area through advanced notice via broadcast notice to mariners and by on-scene designated representatives.

(d) *Enforcement period.* This section will be enforced from 11 a.m. to 3 p.m. on June 2, 2024.

Dated: May 10, 2024.

J.A. Stockwell,

Captain, U.S. Coast Guard, Captain of the Port, Sector Virginia.

[FR Doc. 2024–10863 Filed 5–16–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[USCG–2024–0344]

RIN 1625–AA00

Safety Zone; Firework Display; Appomattox River, Hopewell, VA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters within a 250-yard radius of a fireworks barge located in the Appomattox River, near City Point, in Hopewell, VA. The purpose of this rulemaking is to ensure the safety of persons and vessels, and to protect the marine environment within the navigable waters proximate to fireworks displays, before, during, and after the scheduled events. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector Virginia.

DATES: This rule is effective from 9:15 p.m. to 10 p.m. on June 29, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2024–0344 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 LCDR Ashley Holm, Chief, Waterways Management Division, Sector Virginia, U.S. Coast Guard; telephone 757–668–5580, email *Ashley.E.Holm@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 5 U.S.C. 553(b). This provision, originally enacted as section 4(a) of the Administrative Procedure Act (APA), 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 it is impracticable to publish an NPRM for a safety zone which must be established by June 29, 2024, to prevent harm from potential navigation and safety hazards created by this event. There is not sufficient time to allow for a notice and comment period prior to the event.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port, Sector Virginia (COTP) has determined that potential hazards associated with fireworks events present a safety concern for anyone within the safety zone. The purpose of this rule is to ensure safety of vessels and people in the navigable waters who might otherwise be in the safety zone before, during, and after the scheduled event.

IV. Discussion of the Rule

This rule establishes a safety zone from 9:15 p.m. until 10:00 p.m. on June 29, 2024. The safety zone will include all navigable waters within 250 yards of the fireworks barge located at latitude 37°18′52″ N, longitude 077°17′12.5″ W, located near City Point in Hopewell, VA. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters during the fireworks display. Hazards associated with this event include potential falling debris and possible fire, explosion, projectile, and burn hazards. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. Advance notifications will be made to affected users of the waterway via Broadcast Notice to Mariners and Local Notice to Mariners.

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 on the size, location, duration, and time-of-day of the safety zone. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

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

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in 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 less than 1 hour that will prohibit entry within 250 yards of a fireworks barge. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—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, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T05–0344 to read as follows:

§ 165.T05–0344 Safety Zone; Firework Display; Appomattox River, Hopewell, VA.

(a) *Location.* The following area is a safety zone: all waters at the confluence of the Appomattox and James Rivers within a 250-yard radius of approximate position of the fireworks barge at latitude 37°18′52″ N, longitude 077°17′12.5″ W, located near City Point in Hopewell, VA.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port (COTP) Sector Virginia in the enforcement of the safety zone.

(c) *Regulations.* (1) No vessel or person is permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

(2) To seek permission to enter, contact the COTP's representative via VHF FM Channel 16. Those in the safety zone must comply with all lawful orders

or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This safety zone will be enforced from 9:15 p.m. to 10 p.m. on June 29, 2024.

Dated: May 10, 2024.

J.A. Stockwell,

Captain, U.S. Coast Guard, Captain of the Port, Sector Virginia.

[FR Doc. 2024–10862 Filed 5–16–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0321]

RIN 1625–AA00

Safety Zone; Lake of the Ozarks Mile Marker 0.1–0.3, Lake of the Ozarks, MO

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all navigable waters of the Lake of the Ozarks at mile marker 0.1 to mile marker 0.3. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by a series of fireworks displays. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Upper Mississippi River or a designated representative.

DATES: This rule is effective from May 25, 2024 through December 31, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2024–0321 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 about this rule, call or email MST1 Benjamin Conger, Sector Upper Mississippi River Waterways Management Division, U.S. Coast Guard; telephone 314–269–2573, email *Benjamin.D.Conger@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 under authority in 5 U.S.C. 553(b)(B). This statutory 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.'' The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable and contrary to the public interest. It is impracticable and contrary to the public interest to publish an NPRM because we must establish this safety zone by May 25, 2024 and lack sufficient time to provide a reasonable comment period and consider those comments before issuing the rule. We must establish the safety zone by May 25, 2024 to guard against potential safety hazards associated with this series of fireworks displays. Potential safety hazards include the accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris.

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 and contrary to the public interest because immediate action is needed to protect against potential hazards from this series of fireworks displays beginning May 25, 2024.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector Upper Mississippi River (COTP) has determined that potential hazards associated with Celebrations Cruise fireworks, on May 25, June 15, July 5, July 6, July 13, July 20, July 27, August 3, August 10, August 17, August 24, August 31, and December 31, 2024, will be a safety concern for anyone within the fallout zone. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone during the fireworks displays.

IV. Discussion of the Rule

This rule establishes a safety zone from May 25 through December 31, 2024. The zone will be enforced from 9:30 p.m. until 10:00 p.m. on each of the following days in 2024: May 25, June 15, July 5, July 6, July 13, July 20, July 27, August 3, August 10, August 17, August 24, August 31, and December 31. The safety zone will cover all navigable waters within the outlined fallout zone, on the Lake of the Ozarks, between Mile Markers 0.1 to 0.3. The duration of enforcement of the 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 transit the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. 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 a series of fireworks displays that impact a one-half mile stretch of the Lake of the Ozarks mile marker 0.1 to mile marker 0.3 on May 25, June 15, July 5, July 6, July 13, July 20, July 27, August 3, August 10, August 17, August 24, August 31, and December 31, 2024 from 9:30 p.m. to 10:00 p.m. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the safety zone, mariners may seek permission to enter the zone.

B. Impact on Small Entities

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

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 that will be enforced from 9:30 p.m. to 10:00 p.m. on May 25, June 15, July 5, July 6, July 13, July 20, July 27, August 3, August 10, August 17, August 24, August 31, and December 31, 2024, that will prohibit entry on the Lake of the Ozarks between MM 0.1 to MM 0.3. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

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, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T08–0321 to read as follows:

§ 165.T08–0321 Safety Zone; Lake of the Ozarks, Mile Markers 0.1–0.3, Lake of the Ozarks, MO.

(a) Location. The following area is a safety zone: all navigable waters of the Lake of the Ozarks at mile marker 0.1 to mile marker 0.3.

(b) Regulations. (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the Captain of the Port Sector Upper Mississippi River (COTP) or the COTP's designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard (USCG) assigned to units under the operational control of the USCG Sector Upper Mississippi River.

(2) To seek permission to enter, contact the COTP or the COTP's designated representative via VHF–FM channel 16, or through USCG Sector Upper Mississippi River at 314–269–2332. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(c) Enforcement period. This safety zone will be enforced from 9:30 p.m. to 10:00 p.m. on May 25, June 15, July 5, July 6, July 13, July 20, July 27, August 3, August 10, August 17, August 24, August 31, and December 31, 2024.

Dated: May 9, 2024.

A.R. Bender,

Captain, U.S. Coast Guard, Captain of the Port Sector Upper Mississippi River.

[FR Doc. 2024–10902 Filed 5–16–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Part 7

[NPS–NCR–37822; PPNCWHHOA1, PPMPSAS1Z.T00000, 244P103601]

RIN 1024–AE89

National Capital Region; Event at President's Park

AGENCY: National Park Service, Interior.

ACTION: Temporary rule.

SUMMARY: The National Park Service is temporarily revising regulations for the National Capital Region. This revision will allow the Society of the First Infantry Division to hold an official dedication ceremony at the First Division Monument in Washington, DC, which is located in an area otherwise closed to demonstrations and special events. The ceremony, including setup

and takedown, will last for no longer than three days, and occur between May 22 and May 29, 2024.

DATES: Effective May 22, 2024 through 11:59 p.m. EDT on May 29, 2024.

FOR FURTHER INFORMATION CONTACT: John Stanwich, National Park Service Liaison to the White House, (202) 219–0322, *john_stanwich@nps.gov.*

SUPPLEMENTARY INFORMATION:

Background

The First Infantry Division Monument is located in President's Park, south of State Place Northwest, between 17th Street Northwest and West Executive Avenue Northwest in Washington, DC, United States. The Society of the First Infantry Division conceived this Monument to honor the valiant efforts of First Division soldiers killed in action in World War I. The Monument was dedicated in 1924 by President Calvin Coolidge with 5,516 names inscribed. The primary feature of the Monument is a Milford granite column from Massachusetts, one of the largest pieces ever taken from a quarry in the United States. Standing atop the pillar is a 15-foot-tall, gilded bronze figure of Victory. Later additions to the Monument commemorate the lives of First Infantry Division soldiers killed in action in subsequent wars. The World War II addition is located on the terrace west of the column was dedicated in 1957. This memorial commemorates the 4,325 First Infantry Division soldiers who died in that conflict, as well as the sacrifices of other units attached to the First Infantry Division during the war. The Vietnam War addition is located on the terrace east of the column and was dedicated in 1977. This memorial commemorates the 3,079 First Infantry Division soldiers who died in that conflict, as well as the service and sacrifices of other units as well. The Desert Storm plaque on the eastern edge of the rectangular flower bed, directly opposite the Vietnam War memorial, was dedicated in 1995. This memorial commemorates the lives of 27 soldiers who died while serving in the Desert Storm operation in Saudi Arabia and Iraq, including the names of members of the Third Brigade of the Second Armored Division, which was attached to the First Infantry Division during the war.

While designing the Desert Storm plaque, the Society of the First Infantry Division developed a long-term plan for future additions to the Monument. Their concept distinguishes between memorials for ''limited actions,'' comparable to Desert Storm, and major conflicts with greater fatalities, such as the then-existing memorials for the three wars. The Society suggested smaller blocks of granite placed around the edge of the flower beds on the east and west sides of the terrace for limited actions. For larger conflicts, the Society suggested memorials along the outside edge of the footprint, replacing the hedge, comparable in size and form to the World War II and Vietnam War memorials.

On January 1, 2021, Congress authorized modifications to the Monument, including the construction of and placement of plaques, to honor the dead of the First Infantry Division in Operation Desert Storm, Operation Iraqi Freedom, Operation New Dawn, and Operation Enduring Freedom. Public Law 116–283—section 1083(a). The statute required the Department of the Army, in collaboration with the Secretary of Defense, to provide to the Society with a list of names to be added to the Monument. Department of the Army policy requires an official campaign to end before the names of soldiers killed in that campaign may be added to the monument. The Iraqi Freedom, New Dawn, and Enduring Freedom campaigns have ended. The Commanding General, First Infantry Division has authorized the Society to add to the Monument the names of 631 soldiers who died during these campaigns, consistent with the Society's long-term plan to allow the Monument to evolve with the history of the First Infantry Division. There will be 439 soldiers named for Operation Iraqi Freedom and Operation New Dawn in Iraq. There will be 192 soldiers named for Operation Enduring Freedom in Afghanistan. The additions to the Monument will include bronze plaques situated on stone plinths that include a dedication, operation, units, and name and rank of each soldier. In addition to adding new plaques for Operations Iraqi Freedom, New Dawn, and Enduring Freedom, the existing plaque for Operation Desert storm, which looks temporary, will be replaced with a new plaque co-located with the others.

The Society intends to hold an official dedication ceremony at the Monument that will last no longer than three days, including setup and takedown of equipment, between May 22 and May 29, 2024. The ceremony will include the official dedication of the plaques and a celebration of the 100th Anniversary of the Monument.

Temporary Rule

The Monument is located within an area that is part of the White House and President's Park, which serves as a private residence and office of the President, a military installation, a museum, a public park, and a national shrine. Given these multiple roles and functions, numerous Federal agencies, including the National Park Service (NPS), Executive Office of the President, U.S. Secret Service, and General Services Administration, work in collaboration to administer and manage this area. Congress established the White House and President's Park as a unit of the National Park System in 1961, and for this reason NPS regulations apply to activities within the park, including activities that occur at the First Division Monument.

NPS regulations at 36 CFR 7.96(g)(3)(i) prohibit demonstrations and special events at the Monument site. The NPS promulgated these regulations in 1970 at the request of the U.S. Secret Service for security reasons explained in a letter from the Secret Service Director to the Department of the Interior dated June 25, 1970. See 35 FR 11485, 11491 (July 17, 1970). The long-standing prohibition on events and demonstrations helps to ensure the security of the adjacent White House complex, and the safety of its occupants and the public.

Remaining cognizant of these security and safety concerns, the NPS intends to allow the Society to conduct the ceremony described above, as a special event at the Monument site, in recognition of the service and ultimate sacrifice paid by the soldiers to be named. The Society expects approximately 100 participants, including members of Gold Star Families and active servicemembers, and related equipment and facilities such as chairs, sound amplification, and portable restrooms. The NPS referred the request to hold the event to the U.S. Secret Service for its security-based judgment, and has received their concurrence that this singular event may take place at during the time frame indicated above. The NPS will manage the event through the issuance of a special use permit under 36 CFR 2.50, with appropriate terms and conditions.

In order to allow for the event, this rule will temporarily revise NPS regulations at 36 CFR 7.96(g)(3)(i) to allow for this event to occur at the Monument site as an exception to the general prohibition on demonstrations and special events. The rule will be effective on May 22, 2024, and expire on May 29, 2024, to create a period of time that the three-day event may occur, including time for setup and takedown of equipment related to the event. The date of the event has not yet been determined, but it will occur sometime within the stated period of time. After

the temporary rule expires on May 29, 2024, NPS regulations at 36 CFR 7.96(g)(3)(i) will revert to their former wording.

Compliance With Other Laws, Executive Orders and Department Policy

Regulatory Planning and Review (Executive Orders 12866 and 13563 and 14094)

Executive Order 12866, as amended by Executive Order 14094, provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that the rule is not significant.

Executive Order 14094 amends Executive Order 12866 and reaffirms the principles of Executive Order 12866 and Executive Order 13563 and states that regulatory analysis should facilitate agency efforts to develop regulations that serve the public interest, advance statutory objectives, and be consistent with Executive Order 12866, Executive Order 13563, and the Presidential Memorandum of January 20, 2021 (Modernizing Regulatory Review). Regulatory analysis, as practicable and appropriate, shall recognize distributive impacts and equity, to the extent permitted by law.

Executive Order 13563 reaffirms the principles of Executive Order 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. Executive Order 13563 directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. The NPS has developed this rule in a manner consistent with these requirements.

Administrative Procedure Act

Because setup for the dedication ceremony has been approved to begin as soon as May 22, 2024, at the request of the Society, and as approved by the Department of the Army and the U.S. Secret Service, there is limited time to authorize this event. For this reason, the NPS is publishing this temporary rule as a final rule. In accordance with the requirements of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)), the NPS has determined that publishing a proposed rule would be impractical because of the short time period available. The NPS also believes that publishing this temporary rule 30 days before it becomes effective would be impractical because of the limited time remaining before May 22, 2024. A 30-day delay in this instance would be unnecessary and contrary to the public interest. Therefore, under the Administrative Procedure Act (5 U.S.C. 553(d)(3)), the NPS has determined that this temporary rule will be effective on the date published in the **Federal Register**.

Regulatory Flexibility Act

This rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Congressional Review Act (CRA)

This rulemaking is not a major rule under 5 U.S.C. 804(2). This rule:

(a) Does not have an annual effect on the economy of $100 million or more.

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act (2 U.S.C. 1531 et seq.)

This rule does not impose an unfunded mandate on State, local, or Tribal governments or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local, or Tribal governments or the private sector. It addresses public use of national park lands, and imposes no requirements on other agencies or governments. A statement containing the information required by the Unfunded Mandates Reform Act is not required.

Takings (Executive Order 12630)

This rule does not effect a taking of private property or otherwise have takings implications under E.O. 12630. A takings implication assessment is not required.

Federalism (Executive Order 13132)

Under the criteria in section 1 of E.O. 13132, the rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. This rule only affects use of federally administered lands and waters. It has no outside effects on other areas. A federalism summary impact statement is not required.

Civil Justice Reform (Executive Order 12988)

This rule complies with the requirements of E.O. 12988. This rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Consultation With Indian Tribes (Executive Order 13175 and Department Policy)

The Department of the Interior strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and Tribal sovereignty. The NPS has evaluated this rule under the criteria in E.O. 13175 and under the Department's Tribal consultation policy and has determined that Tribal consultation is not required because the rule will not have a substantial direct effect on federally recognized Indian Tribes.

Paperwork Reduction Act

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget under the Paperwork Reduction Act is not required. The NPS may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act of 1969 (NEPA)

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the NEPA is not required because the rule is covered by a categorical exclusion. NPS Handbook 2015 section 3.3.A.8. We have also determined that the rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under the NEPA.

Effects on the Energy Supply (Executive Order 13211)

This rule is not a significant energy action under the definition in Executive

Order 13211. A Statement of Energy Effects in not required.

List of Subjects in 36 CFR Part 7

District of Columbia, National parks, Reporting and recordkeeping requirements.

In consideration of the foregoing, the National Park Service amends 36 CFR part 7 as set forth below:

PART 7—SPECIAL REGULATIONS, AREAS OF THE NATIONAL PARK SYSTEM

■ 1. The authority citation for part 7 continues to read as follows:

Authority: 54 U.S.C. 100101, 100751, 320102; Sec. 7.96 also issued under D.C. Code 10–137 and D.C. Code 50–2201.07.

§ 7.96 [Amended]

■ 2. In the last sentence of § 7.96(g)(3)(i), add the words '', and except for an official dedication ceremony at the First Infantry Division Monument to last no more than three days, including setup and takedown of equipment, between May 22 and May 29, 2024'' after the word ''Park''.

Shannon A. Estenoz,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2024–10836 Filed 5–16–24; 8:45 am]

BILLING CODE 4312–52–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 282

[EPA–R07–UST–2023–0491; FRL–11446–02–R7]

Missouri: Final Approval of State Underground Storage Tank Program Revisions, Codification, and Incorporation by Reference

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: Pursuant to the Resource Conservation and Recovery Act (RCRA or Act), the Environmental Protection Agency (EPA) is taking direct final action to approve revisions to the State of Missouri's Underground Storage Tank (UST) program submitted by the Missouri Department of Natural Resources (MDNR). This action also codifies EPA's approval of Missouri's State program and incorporates by reference those provisions of the State regulations that we have determined meet the requirements for approval. The provisions will be subject to EPA's inspection and enforcement authorities under RCRA and other applicable statutory and regulatory provisions.

DATES: This rule is effective July 16, 2024, unless EPA receives adverse comment by June 17, 2024. If EPA receives adverse comments, it will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register, as of July 16, 2024, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

ADDRESSES: Submit your comments by one of the following methods:

1. *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the on-line instructions for submitting comments.

2. *Email: drouare.douglas@epa.gov*.

Instructions: Direct your comments to Docket ID No. EPA–R07–UST–2023–0491. EPA's policy is that all comments received will be included in the public docket without change and may be available online at *https://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *https://www.regulations.gov,* or email. The Federal *https://www.regulations.gov* website is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *https://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and also with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties, and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. EPA encourages electronic submittals, but if you are unable to submit electronically, please reach out to the EPA contact person listed in the document for assistance.

Docket: All documents in the docket are listed in the *https://www.regulations.gov* index. Although listed in the index, some information might not be publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Publicly available docket materials are available electronically through *https://www.regulations.gov*.

IBR and supporting material: You can view and copy the documents that form the basis for this codification and associated publicly available materials either through *https://www.regulations.gov* or by contacting Douglas Drouare at (913) 551–7299 or *drouare.douglas@epa.gov*. Please call or email the contact listed above if you need access to material indexed but not provided in the docket.

FOR FURTHER INFORMATION CONTACT: Douglas E. Drouare, Tanks, Toxics, and Pesticides Branch, Land, Chemical, and Redevelopment Division, U.S. Environmental Protection Agency, Region 7, 11201 Renner Boulevard, Lenexa, Kansas 66219; telephone number: (913) 551–7299; email address: *drouare.douglas@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Approval of Revisions to Missouri's Underground Storage Tank Program

A. Why are revisions to State programs necessary?

States that have received final approval from the EPA under section 9004(b) of RCRA, 42 U.S.C. 6991c(b), must maintain an underground storage tank program that is equivalent to, consistent with, and no less stringent than the Federal UST program. Either EPA or the approved State may initiate program revision. When EPA makes revisions to the regulations that govern the UST program, States must revise their programs to comply with the updated regulations and submit these revisions to the EPA for approval. Program revision may be necessary when the controlling Federal or State statutory or regulatory authority is modified or when responsibility for the State program is shifted to a new agency or agencies.

B. What decisions has the EPA made in this rule?

On August 11, 2023, in accordance with 40 CFR 281.51(a), Missouri submitted a complete program revision application seeking the EPA approval for its UST program revisions (State Application). Missouri's revisions correspond to the EPA final rule

published on July 15, 2015 (80 FR 41566), which revised the 1988 UST regulations and the 1988 State program approval (SPA) regulations (2015 Federal Revisions). As required by 40 CFR 281.20, the State Application contains the following: a transmittal letter requesting approval, a description of the program and operating procedures, a demonstration of the State's procedures to ensure adequate enforcement, a Memorandum of Agreement outlining the roles and responsibilities of the EPA and the implementing agency, a statement of certification from the Attorney General, and copies of all relevant State statutes and regulations. We have reviewed the State Application and determined that the revisions to Missouri's UST program are equivalent to, consistent with, and no less stringent than the corresponding Federal requirements in subpart C of 40 CFR part 281, and that the Missouri program provides for adequate enforcement of compliance (40 CFR 281.11(b)). Therefore, the EPA grants Missouri final approval to operate its UST program with the changes described in the program revision application and as outlined below in section I.G. of this document.

C. What is the effect of this approval decision?

This action does not impose additional requirements on the regulated community because the regulations being approved by this rule are already effective in Missouri and they are not changed by this action. This action merely approves the existing State regulations as meeting the Federal requirements and renders them federally enforceable.

D. Why is EPA using a direct final rule?

EPA is publishing this direct final rule concurrent with a proposed rule because we view this as a noncontroversial action and anticipate no adverse comment. EPA is providing an opportunity for public comment now.

E. What happens if the EPA receives comments that oppose this action?

Along with this direct final rule, the EPA is publishing a separate document in the ''Proposed Rules'' section of this issue of the **Federal Register** that serves as the proposal to approve the State's UST program revisions, providing opportunity for public comment. If EPA receives comments that oppose this approval, EPA will withdraw the direct final rule by publishing a document in the **Federal Register** before the rule becomes effective. The EPA will base any further decision on the approval of the State program changes after considering all comments received during the comment period. EPA will then address all public comments in a later final rule. You may not have another opportunity to comment. If you want to comment on this approval, you must do so at this time.

F. For what has Missouri previously been approved?

On May 5, 2004, the EPA finalized a rule approving the UST program, effective June 5, 2004, to operate in lieu of the Federal program. The State's program has not previously been codified.

G. What changes are we approving with this action?

On August 11, 2023, in accordance with 40 CFR 281.51(a), Missouri submitted a complete application for final approval of its UST program revisions adopted on May 17, 2017. The EPA now makes an immediate final decision, subject to receipt of written comments that oppose this action, that Missouri's UST program revisions satisfy all of the requirements necessary to qualify for final approval. Therefore, EPA grants Missouri final approval for the following program changes:

Required Federal element	Implementing State authority
40 CFR 281.30, New UST Systems and Notification	10 CSR 26–2.019, 2.020 & 2.022.
40 CFR 281.31, Upgrading Existing UST Systems	10 CSR 26–2.021.
40 CFR 281.32, General Operating Requirements	10 CSR 26–2.030 through 2.036.
40 CFR 281.33, Release Detection	10 CSR 26–2.040 through 2.048.
40 CFR 281.34, Release Reporting, Investigation, and Confirmation	10 CSR 26–2.050 through 2.053.
40 CFR 281.35, Release Response and Corrective Action	10 CSR 26–2.070 through 2.083.
40 CFR 281.36, Out-of-service Systems and Closure	10 CSR 26–2.060 through 2.064.
40 CFR 281.37, Financial Responsibility for USTs Containing Petroleum.	10 CSR 26–3 and 10 CSR 100–1 through 100–6.
40 CFR 281.39, Operator Training	10 CSR 100–6
40 CFR 281.41, Legal Authorities for Enforcement Response	10 CSR 26–4, Missouri Revised Statutes, Chapters 260, 319, 507, 644 and Missouri Supreme Court Rules, Rule 52, Rules of Civil Procedure.

The State also demonstrates that its program provides adequate enforcement of compliance as described in 40 CFR 281.11(b) and part 281, subpart D. The MDNR has broad statutory authority with respect to USTs to regulate installation, operation, maintenance, closure, and UST releases, and to the issuance of orders. These statutory authorities are found in: Missouri Revised Statutes, Chapters 260, 319, 507, 644, and Missouri Supreme Court Rules—Rule 52 and Missouri Rules (regulations) of Department of Natural Resources, Divisions 26 and 100.

H. Where are the revised rules different from the Federal rules?

Broader in Scope Provisions

The following statutory and regulatory provisions are considered broader in scope than the Federal program, and are therefore not enforceable as a matter of Federal law pursuant to 40 CFR 281.12(a)(3)(ii):

Missouri Revised Statutes

Revised Statutes of Missouri, RSMo section 260

Revised Statutes of Missouri, RSMo section 319.100

Revised Statutes of Missouri, RSMo section 319.103

Revised Statutes of Missouri, RSMo section 319.105

Revised Statutes of Missouri, RSMo section 319.107

Revised Statutes of Missouri, RSMo section 319.109

Revised Statutes of Missouri, RSMo section 319.111

Revised Statutes of Missouri, RSMo section 319.114

Revised Statutes of Missouri, RSMo section 319.117

Revised Statutes of Missouri, RSMo section 319.120

Revised Statutes of Missouri, RSMo section 319.123
Revised Statutes of Missouri, RSMo section 319.125
Revised Statutes of Missouri, RSMo section 319.127
Revised Statutes of Missouri, RSMo section 319.129
Revised Statutes of Missouri, RSMo section 319.130
Revised Statutes of Missouri, RSMo section 319.131
Revised Statutes of Missouri, RSMo section 319.132
Revised Statutes of Missouri, RSMo section 319.133
Revised Statutes of Missouri, RSMo section 319.135
Revised Statutes of Missouri, RSMo section 319.136
Revised Statutes of Missouri, RSMo section 319.137
Revised Statutes of Missouri, RSMo section 319.138
Revised Statutes of Missouri, RSMo section 319.139
Revised Statutes of Missouri, RSMo section 319.140
Revised Statutes of Missouri, RSMo section 507
Revised Statutes of Missouri, RSMo section 644

Missouri Code of State Regulations

Title 10—Department of Natural Resources

Division 26—Petroleum and Hazardous Substance Storage Tanks

Rules of Department of Natural Resources, Division 26—Petroleum and Hazardous Substance Storage Tanks, Chapter 1—Underground and Aboveground Storage Tanks—Organization
Rules of Department of Natural Resources, Division 26—Petroleum and Hazardous Substance Storage Tanks, Chapter 4—Underground Storage Tanks—Administrative Penalties
Rules of Department of Natural Resources, Division 26—Petroleum and Hazardous Substance Storage Tanks, Chapter 5—Aboveground Storage Tanks—Release Response

Division 100—Petroleum Storage Tank Insurance Fund Board of Trustees

Rules of Department of Natural Resources, Division 100—Petroleum Storage Tank Insurance Fund Board of Trustees, Chapter 1—General Organization
Rules of Department of Natural Resources, Division 100—Petroleum Storage Tank Insurance Fund Board of Trustees, Chapter 2—Definitions
Rules of Department of Natural Resources, Division 100—Petroleum Storage Tank Insurance Fund Board of Trustees, Chapter 3—Transport Load Fee
Rules of Department of Natural Resources, Division 100—Petroleum Storage Tank Insurance Fund Board of Trustees, Chapter 4—Participation Requirements
Rules of Department of Natural Resources, Division 100—Petroleum Storage Tank Insurance Fund Board of Trustees, Chapter 5—Claims

More Stringent Provisions

The following regulatory requirements are considered more stringent than the Federal program, and on approval, they become part of the federally approved program and are federally enforceable pursuant to 40 CFR 281.12(a)(3)(i):

Missouri has removed some federally allowed exceptions to corrosion protection making them more stringent: 10 CSR 26–2.020, 1, (A) & (B).

Missouri makes a number of stipulations requiring corrosion protection for all metal coming in contact with any ''electrolyte'' making them more stringent: 10 CSR 26–2.020 (B) and 10 CSR–2.021, (4).

Missouri has set a compliance date for new underground storage tank system performance standards of July 1, 2017 which would be earlier than Federal regulatory requirement making them more stringent: 10 CSR 26–2.020 (A), (A).5, (B), (B).3, (B).5 & (C).1.B,(III).(c).

Missouri is more prescriptive and offers fewer options than Federal regulations for certification of installation making them more stringent: 10 CSR 26–2.022.

Missouri has more restrictive thresholds (volumetric and timing) for overfill devices and alarms than Federal regulations making them more stringent: 10 CSR 26–2.020 (C).B.(II).

Missouri is more prescriptive than Federal regulations as to when ball float valves can and cannot be utilized for overfill prevention making them more stringent: 10 CSR 26–2.020 (C).B.(III).

Missouri is more prescriptive than Federal regulations regarding compatibility and approval of overfill devices utilized for pressurized delivery systems making them more stringent: 10 CSR 26–2.020 (C).B.(IV).

Missouri offers fewer acceptable standards and practices for spill and overfill prevention than Federal regulations making them more stringent: 10 CSR 26–2.030 (9).

Missouri has added operation and maintenance of corrosion protection reporting (performance logs, testing reports) and action (what to do if tests fail, cathodic protection found off or not working) criteria that is more specific than Federal regulations making them more stringent: 10 CSR 26–2.031 (B), (C) and (D).

Missouri regulations indicate that documents demonstrating compatibility of all UST systems, including tanks, piping, release detection equipment and all other ancillary equipment with the regulated substance being stored are required. This is more expansive and stringent than Federal regulations: 10 CSR 26–2.034 (1).(B).3.

Missouri has a more restricted list of allowable standards and practices for repairs allowed than Federal regulations making them more stringent: 10 CSR 26–2.033, (2).(A).1.

Missouri specifies that when repairing cathodically protected metal piping that released a regulated substance, the entire length of electrically continuous pipe must be replaced. This is more expansive and stringent than Federal regulations: 10 CSR 26–2.033, (2).(C).

Missouri specifies repairs must be done by a person registered with the Missouri Department of Agriculture and who has a financial responsibility mechanism. This is more expansive and stringent than Federal regulations: 10 CSR 26–2.033, (2).(D).

Missouri is more prescriptive in details and criteria regarding testing of containment sumps. In addition, Missouri requires testing of all containment sumps. This is more expansive and stringent than Federal regulations: 10 CSR 26–2.035, (1) and (2).

Missouri requires walkthrough inspections immediately for new underground storage tank installs. There is not a lessening in frequency if deliveries are received less than every thirty days. This is more stringent than Federal regulations: 10 CSR 26–2.036, (1), (C), 1.

Missouri does not allow groundwater or vapor monitoring for release detection after July 1, 2020; except where vapor monitoring is accompanied by a tracer chemical. This is more stringent than Federal regulations: 10 CSR 26–2.041, (1), (A), 4 and 5.

Missouri stipulates that interstitial monitoring can only be performed with a double-walled tank: not with systems with secondary barriers or internal linings. This is more stringent than Federal regulations: 10 CSR 26–2.043, (1), (H).

Missouri allows for only 24 hours for completion of initial release response action. There is no flexibility on the timing. This is more stringent than Federal regulations: 10 CSR 26–2.071, (1).

Missouri allows for only 20 days for completion of initial abatement actions. There is no flexibility on the timing. This is more stringent than Federal regulations: 10 CSR 26–2.072, (2).

Missouri allows for only 45 days for completion of site characterization actions. There is no flexibility on the timing. This is more stringent than Federal regulations: 10 CSR 26–2.074, (2).

Missouri does not to allow temporary underground storage tank closures with product in the tank. This is more stringent than Federal regulations: 10 CSR 26–2.012, (1), O, 4.

Missouri requires permanent closure after 5 years of out of service or out of use status. This is more stringent than Federal regulations: 10 CSR 26–2.060, (4).

Missouri has prescriptive requirements for bringing an out of service or out of use underground storage tank back into service or use. This is more stringent than Federal regulations: 10 CSR 26–2.060, (5), (6) and (7).

Missouri has a notification requirement for out of service or out of use underground storage tank status changes. This is more stringent than Federal regulations: 10 CSR 26–2.060, (9).

Missouri does not allow leak detection equipment/methods to be used to meet the assessing the site at closure or change in service requirement. A written procedure for sampling and testing must be followed. This is more stringent than Federal regulations: 10 CSR 26–2.062.

Missouri regulations have a definition of ''corrosion expert'' that is limited to those with a National Association of Corrosion Engineers International certification. This is more stringent than Federal regulations: 10 CSR 26–2.012, (1), (C), 7.

Missouri regulations have a definition of ''replaced'' as it pertains to piping that includes the language ''or single compartment'' that addresses specific situations involving compartmentalized underground storage tanks. This is more stringent than Federal regulations: 10 CSR 26–2.012, (1), (R), 5, B.

Missouri regulations have a definition of ''septic tank'' that includes the language ''and constructed''. This is more stringent than Federal regulations: 10 CSR 26–2.012, (1), (S), 3.

II. Codification

A. What is codification?

Codification is the process of placing a State's statutes and regulations that comprise the State's approved UST program into the CFR. Section 9004(b) of RCRA, as amended, allows the EPA to approve State UST programs to operate in lieu of the Federal program. The EPA codifies its authorization of State programs in 40 CFR part 282 and incorporates by reference State statutes and regulations that the EPA will enforce under sections 9005 and 9006 of RCRA and any other applicable State provisions. The incorporation by reference of State authorized programs in the CFR should substantially enhance the public's ability to discern the current status of the approved State program and State requirements that can be federally enforced. This effort provides clear notice to the public of the scope of the approved program in each State.

B. What is the history of codification of Missouri's UST program?

The EPA has not previously incorporated by reference and codified State's approved UST program. Through this action, the EPA is incorporating by reference and codifying State's State program in 40 CFR 282.75 to include the program and the approved revisions.

C. What codification decisions have we made in this rule?

Incorporation by reference: In this rule, we are finalizing regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, we are finalizing the incorporation by reference of the federally approved Missouri UST program described in the amendments to 40 CFR part 282 set forth below. The EPA has made, and will continue to make, this document generally available through *https://www.regulations.gov* or by contacting the EPA Region 7 contact listed in the **ADDRESSES** section of this preamble.

The purpose of this **Federal Register** document is to codify Missouri's approved UST program. The codification reflects the State program that would be in effect at the time EPA's approved revisions to the Missouri UST program addressed in this direct final rule become final. The document incorporates by reference Missouri's UST statutes and regulations and clarifies which of these provisions are included in the approved and federally enforceable program. By codifying the approved Missouri program and by amending the CFR, the public will more easily be able to discern the status of the federally-approved requirements of the Missouri program.

EPA is incorporating by reference the Missouri approved UST program in 40 CFR 282.75. Section 282.75(d)(1)(i) incorporates by reference for enforcement purposes the State's statutes and regulations.

Section 282.75 also references the Attorney General's Statement, Demonstration of Adequate Enforcement Procedures, the Program Description, and the Memorandum of Agreement, which are approved as part of the UST program under Subtitle I of RCRA. These documents are not incorporated by reference.

D. What is the effect of Missouri's codification on enforcement?

The EPA retains the authority under sections 9005 and 9006 of Subtitle I of RCRA, 42 U.S.C. 6991d and 6991e, and other applicable statutory and regulatory provisions to undertake inspections and enforcement actions and to issue orders in approved States. With respect to these actions, EPA will rely on Federal sanctions, Federal inspection authorities, and Federal procedures rather than the State authorized analogues to these provisions. Therefore, the EPA is not incorporating by reference such particular, approved Missouri procedural and enforcement authorities. Section 282.75(d)(1)(ii) of 40 CFR lists those approved Missouri authorities that would fall into this category.

E. What State provisions are not part of the codification?

The public also needs to be aware that some provisions of the State's UST program are not part of the federally approved State program. Such provisions are not part of the RCRA Subtitle I program because they are ''broader in scope'' than Subtitle I of RCRA. Section 281.12(a)(3)(ii) of 40 CFR states that where an approved State program has provisions that are broader in scope than the Federal program, those provisions are not a part of the federally approved program. As a result, State provisions which are broader in scope than the Federal program are not incorporated by reference for purposes of Federal enforcement in part 282. Section 282.75(d)(1)(iii) lists for reference and clarity the Missouri statutory and regulatory provisions which are broader in scope than the Federal program and which are not, therefore, part of the approved program being codified in this document. Provisions that are broader in scope cannot be enforced by EPA; the State, however, will continue to implement and enforce such provisions under State law.

III. Statutory and Executive Order Reviews

This action only applies to Missouri's UST Program requirements pursuant to RCRA section 9004 and imposes no requirements other than those imposed by State law. It complies with applicable Executive Orders (EOs) and statutory provisions as follows. Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This action is not a significant regulatory action as defined in Executive Order 12866 (58 FR 51735, October 4, 1993), as amended by Executive Order 14094 (88 FR 21879, April 11, 2023), because this action approves and codifies State requirements for the purpose of RCRA section 9004 and imposes no additional requirements beyond those imposed by State law. Therefore, this action was not subject to a requirement for Executive Order 12866 review.

B. Paperwork Reduction Act (PRA)

This rule does not impose an information collection burden under the provisions of the PRA, 44 U.S.C. 3501 *et seq.* Burden is defined at 5 CFR 1320.3(b).

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.,* because this action authorizes State requirements pursuant to RCRA section 9004 and imposes no requirements beyond those imposed by State law.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandates as described in UMRA, 2 U.S.C. 1501 *et seq.,* and does not significantly or uniquely affect small governments because this action approves and codifies pre-existing requirements under State law and does not impose any additional enforceable duty beyond that required by State law.

E. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67429, November 9, 2000) because currently there are no federally recognized Tribes in Pennsylvania. Thus, Executive Order 13175 does not apply to this action.

F. Executive Order 13132: Federalism

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely approves and codifies State requirements as part of the State RCRA underground storage tank program without altering the relationship or the distribution of power and responsibilities established by RCRA.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. Therefore, this action is not subject to Executive Order 13045 because it approves a State program.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not a ''significant regulatory action'' as defined under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

Under RCRA section 9004(b), EPA grants a State's application for approval as long as the State meets the criteria required by RCRA. It would thus be inconsistent with applicable law for EPA, when it reviews a State approval application, to require the use of any particular voluntary consensus standard in place of another standard that otherwise satisfies the requirements of RCRA. Thus, the requirements of section 12(d) of the NTTAA, 15 U.S.C. 272 note, do not apply to this action.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations (people of color and/or Indigenous peoples) and low-income populations. Because this action approves pre-existing State rules that are no less stringent than existing Federal requirements and imposes no additional requirements beyond those imposed by State law, and there are no anticipated significant adverse human health or environmental effects, this rule is not subject to Executive Order 12898.

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.,* and EPA will submit a rule report containing this document and other required information to each House of the Congress and the Comptroller General of the United States prior to publication 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). However, this action will be effective July 16, 2024 because it is a direct final rule.

Authority: This rule is issued under the authority of sections 2002(a), 7004(b), and 9004 of the Solid Waste Disposal Act, as amended, 42 U.S.C. 6912, 6991c, 6991d, and 6991e.

List of Subjects in 40 CFR Part 282

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous substances, Incorporation by reference, Insurance, Intergovernmental relations, Oil pollution, Penalties, Petroleum, Reporting and recordkeeping requirements, Surety bonds, Water pollution control, Water supply.

Dated: May 9, 2024.

Meghan McCollister,

Regional Administrator, EPA Region 7.

For the reasons set forth in the preamble, EPA is amending 40 CFR part 282 as follows:

PART 282—APPROVED UNDERGROUND STORAGE TANK PROGRAMS

■ 1. The authority citation for part 282 continues to read as follows:

Authority: 42 U.S.C. 6912, 6991c, 6991d, and 6991e.

■ 2. Add § 282.75 to read as follows:

§ 282.75 Missouri State-Administered Program.

(a) *History of the approval of Missouri's program.* The State of Missouri is approved to administer and enforce an underground storage tank program in lieu of the Federal program under Subtitle I of the Resource Conservation and Recovery Act of 1976 (RCRA), as amended, 42 U.S.C. 6991 *et seq.* The State's program, as administered by the Missouri Department of Natural Resources, was approved by EPA pursuant to 42 U.S.C. 6991c and part 281 of this Chapter. EPA approved the Missouri program on May 5, 2004 and it was effective on June 5, 2004. A subsequent program revision application was approved by EPA and became effective on July 16, 2024.

(b) *Enforcement authority.* Missouri has primary responsibility for administering and enforcing its federally approved underground storage tank program. However, EPA retains the authority to exercise its inspection and enforcement authorities under sections 9005 and 9006 of Subtitle I of RCRA, 42 U.S.C. 6991d and 6991e, as well as under any other applicable statutory and regulatory provisions.

(c) *Retaining program approval.* To retain program approval, Missouri must revise its approved program to adopt new changes to the federal Subtitle I program which makes it more stringent, in accordance with section 9004 of RCRA, 42 U.S.C. 6991c and 40 CFR part 281, subpart E. If Missouri obtains approval for the revised requirements pursuant to section 9004 of RCRA, 42 U.S.C. 6991c, the newly approved statutory and regulatory provisions will be added to this subpart and notice of any change will be published in the **Federal Register**.

(d) *Final program approval.* Missouri has final approval for the following elements of its program application originally submitted to EPA and approved on May 5, 2004 and effective June 5, 2004, and the program revision application approved by EPA, effective on July 16, 2024:

(1) *State statutes and regulations*—(i) *Incorporation by reference.* The provisions cited in this paragraph, and listed in appendix A to part 282, are incorporated by reference as part of the underground storage tank program under Subtitle I of RCRA, 42 U.S.C. 6991 *et seq.* The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. This material is available for inspection at the EPA and at the National Archives and Records Administration (NARA). You may inspect all approved material at the EPA Region 7 Office, 11201 Renner Boulevard, Lenexa, KS 66219; phone number: (913) 551–7299. For information on the availability of this material at NARA, email: *fr.inspection@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.* You may obtain copies of the Missouri regulations and statutes that are incorporated by reference in this paragraph from the Missouri Department of Natural Resources website at: *https://www.dnr.mo.gov/waste-recycling/business-industry/guidance-technical-assistance/underground-storage-tank-requirements, https://www.dnr.mo.gov/waste-recycling/investigations-cleanups/regulated-storage-tank-closure* or the Missouri Department of Natural Resources, Underground Storage Tanks Section, P.O. Box 176, Jefferson City, Missouri, 65102–0176; phone number: (573) 751–6822.

(A) EPA-Approved Missouri Statutory Requirements Applicable to the Underground Storage Tank Program, May 2017.

(B) EPA-Approved Missouri Regulatory Requirements Applicable to the Underground Storage Tank Program, May 2017.

(ii) *Legal basis.* EPA evaluated the following statutes and regulations, which provide the legal basis for the State's implementation of the underground storage tank program, but they are not being incorporated by reference for enforcement purposes and do not replace Federal authorities. Missouri's no less stringent underground storage tank program compliance criteria is included in their regulations. Missouri includes brief statements in their statutes establishing the authority of the Missouri Department of Natural Resources to create and implement the underground storage tank program. None of these statutes are incorporated by reference.

(A) Revised Statutes of Missouri, RSMo section 260.

(B) Revised Statutes of Missouri, RSMo sections 319.100, 319.103, 319.105, 319.107, 319.109, 319.111, 319.114, 319.117, 319.120, 319.123, 319.125, 319.127, 319.129, 319.130, 319.131, 319.132, 319.133, 319.135, 319.136, 319.137, 319.138, 319.139, 319.140.

(C) Revised Statutes of Missouri, RSMo section 507.

(D) Revised Statutes of Missouri, RSMo section 644.

(E) Missouri Supreme Court Rules—Rule 52—Rules of Civil Procedure.

(F) Rules of Department of Natural Resources, Division 26—Chapters 1 and 4.

(G) Rules of Department of Natural Resources, Division 100—Chapters 1 through 5.

(iii) *Provisions not incorporated by reference.* The following statutory and regulatory provisions are broader in scope than the Federal program, are not part of the approved program, and are not incorporated by reference in this section for enforcement purposes:

(A) Missouri Revised Statutes.

(*1*) Revised Statutes of Missouri, RSMo section 260.

(*2*) Revised Statutes of Missouri, RSMo sections 319.100, 319.103, 319.105, 319.107, 319.109, 319.111, 319.114, 319.117, 319.120, 319.123, 319.125, 319.127, 319.129, 319.130, 319.131, 319.132, 319.133, 319.135, 319.136, 319.137, 319.138, 319.139, 319.140.

(*3*) Revised Statutes of Missouri, RSMo section 507.

(*4*) Revised Statutes of Missouri, RSMo section 644.

(B) Missouri Code of State Regulations.

(*1*) Rules of Department of Natural Resources, Division 26—Chapters 1, 4 and 5.

(*2*) Rules of Department of Natural Resources, Division 100—Chapters 1 through 5.

(2) *Statement of legal authority.* The ''Attorney General's Statement'', signed by the Missouri Attorney General on May 5, 2004, and August 11, 2023, though not incorporated by reference, is referenced as part of the approved underground storage tank program under Subtitle I of RCRA, 42 U.S.C. 6991 *et seq.*

(3) *Demonstration of procedures for adequate enforcement.* The ''Adequate Enforcement of Compliance'' submitted as part of the original application on May 5, 2004, and as part of the program revision application on August 11, 2023, though not incorporated by reference, is referenced as part of the approved underground storage tank program under Subtitle I of RCRA, 42 U.S.C. 6991 *et seq.*

(4) *Program description.* The program description and any other material submitted as part of the original application on May 5, 2004, and as part of the program revision application on August 11, 2023, though not incorporated by reference, are referenced as part of the approved underground storage tank program under Subtitle I of RCRA, 42 U.S.C. 6991 *et seq.*

(5) *Memorandum of Agreement.* The Memorandum of Agreement between EPA Region 7 and the State of Missouri, signed by the EPA Regional Administrator on April 15, 2019, though

not incorporated by reference, is referenced as part of the approved underground storage tank program under Subtitle I of RCRA, 42 U.S.C. 6991 *et seq.*

■ 3. In appendix A to part 282 add in alphabetical order the entry ''Missouri'' to read as follows:

Appendix A to Part 282—State Requirements Incorporated by Reference in Part 282 of the Code of Federal Regulations

* * * * *

Missouri

(a) The statutory provisions include: None.

(b) The regulatory provisions include:

Rules of Department of Natural Resources, Division 2—Petroleum and Hazardous Substance Storage Tanks, Chapter 2—Underground Storage Tanks—Technical Regulations, *except for:*

10 CSR 26–2.020, 1, (A) and (B) language that removed some federally allowed exceptions to corrosion protection making them more stringent.

10 CSR 26–2.020 (B) and 10 CSR–2.021, (4) language that makes a number of stipulations requiring corrosion protection for all metal coming in contact with any ''electrolyte'' making them more stringent.

10 CSR 26–2.020 (A), (A).5, (B), (B).3, (B).5 and (C).1.B,(III).(c) language that stipulates a compliance date for new underground storage tank system performance standards of July 1, 2017 which would be earlier than Federal regulatory requirement making them more stringent.

10 CSR 26–2.022 language that stipulates fewer options than Federal regulations for certification of installation making them more stringent.

10 CSR 26–2.020 (C).B.(II) language that stipulates more restrictive thresholds (volumetric and timing) for overfill devices and alarms than Federal regulations making them more stringent.

10 CSR 26–2.020 (C).B.(III) language that stipulates more prescriptive uses of ball float valves making them more stringent.

10 CSR 26–2.020 (C).B.(IV) language that stipulates more prescriptive regulations regarding compatibility and approval of overfill devices utilized for pressurized delivery systems making them more stringent.

10 CSR 26–2.030 (9) language that stipulates fewer acceptable standards and practices for spill and overfill prevention making them more stringent.

10 CSR 26–2.031 (B), (C) and (D) language that added operation and maintenance of corrosion protection reporting (performance logs, testing reports) and action (what to do if tests fail, cathodic protection found off or not working) criteria that is more specific than Federal regulations making them more stringent.

10 CSR 26–2.034 (1).(B).3 language that stipulates documents demonstrating compatibility of all UST systems, including tanks, piping, release detection equipment and ''all other ancillary equipment'' with the regulated substance being stored are required. This is more expansive and stringent than Federal regulation.

10 CSR 26–2.033, (2).(A).1 language that stipulates a more restricted list of allowable standards and practices for repairs allowed than Federal regulations making them more stringent.

10 CSR 26–2.033, (2).(C) language that stipulates when repairing cathodically protected metal piping that released a regulated substance, the entire length of electrically continuous pipe must be replaced. This is more expansive and stringent than Federal regulations.

10 CSR 26–2.033, (2).(D) language that stipulates repairs must be done by a person registered with the Missouri Department of Agriculture and who has a financial responsibility mechanism. This is more expansive and stringent than Federal regulations.

10 CSR 26–2.035, (1) and (2) language that stipulates the testing of all containment sumps. This is more expansive and stringent than Federal regulations.

10 CSR 26–2.036, (1), (C), 1 language that requires an immediate walkthrough inspection for new underground storage tank installs and no lessening in frequency of walkthrough inspections if deliveries are received less than every thirty days. This is more stringent than Federal regulations.

10 CSR 26–2.041, (1), (A), 4 and 5 language that does not allow groundwater or vapor monitoring for release detection after July 1, 2020; except where vapor monitoring is accompanied by a tracer chemical. This is more stringent than Federal regulations.

10 CSR 26–2.043, (1), (H). language that stipulates interstitial monitoring can only be performed with a double-walled tank: not with systems with secondary barriers or internal linings. This is more stringent than Federal regulations.

10 CSR 26–2.071, (1) language that stipulates only 24 hours for completion of initial release response action. There is no flexibility on the timing. This is more stringent than Federal regulations.

10 CSR 26–2.072, (2) language that stipulates only 20 days for completion of initial abatement actions. There is no flexibility on the timing. This is more stringent than Federal regulations.

10 CSR 26–2.074, (2) language that stipulates only 45 days for completion of site characterization actions. There is no flexibility on the timing. This is more stringent than Federal regulations.

10 CSR 26–2.012, (1), O, 4 language that does not allow temporary underground storage tank closures with product in the tank. This is more stringent than Federal regulations.

10 CSR 26–2.060, (4) language that requires permanent closure after 5 years of out of service or out of use status. This is more stringent than Federal regulations.

10 CSR 26–2.060, (5), (6) and (7) language that stipulates prescriptive requirements for bringing an out of service or out of use underground storage tank back into service or use. This is more stringent than Federal regulations.

10 CSR 26–2.060, (9) language that stipulates a notification requirement for out of service or out of use underground storage tank status changes. This is more stringent than Federal regulations.

10 CSR 26–2.062 language that stipulates leak detection equipment/methods cannot be used to meet the assessing the site at closure or change in service requirements. A written procedure for sampling and testing must be followed. This is more stringent than Federal regulations.

10 CSR 26–2.012, (1), (C), 7 language that stipulates a ''corrosion expert'' is limited to those with a National Association of Corrosion Engineers International certification. This is more stringent than Federal regulations.

10 CSR 26–2.012, (1), (R), 5, B language that stipulates a definition of ''replaced'' as it pertains to piping that includes the language ''or single compartment'' that addresses specific situations involving compartmentalized underground storage tanks. This is more stringent than Federal regulations.

10 CSR 26–2.012, (1), (S), 3 language that stipulates a definition of ''septic tank'' that includes the language ''and constructed''. This is more stringent than Federal regulations.

Rules of Department of Natural Resources, Division 26—Petroleum and Hazardous Substance Storage Tanks, Chapter 3—Underground Storage Tanks—Financial Responsibility

Rules of Department of Natural Resources, Division 100—Petroleum Storage Tank Insurance Fund Board of Trustees, Chapter 6—UST Operator Training

* * * * *

[FR Doc. 2024–10775 Filed 5–16–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA–HQ–OPP–2020–0546; FRL–11674–01–OCSPP]

Bacillus Thuringensis Cry1B.868 and Cry1Da_7 Proteins; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the *Bacillus thuringensis* Cry1B.868 and Cry1Da_7 proteins (hereafter Cry1B.868 and Cry1Da_7) when used as a Plant-Incorporated Protectant (PIP) in or on the food and feed commodities of corn: corn, field; corn, sweet, and corn, pop. Bayer U.S.—Crop Science submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to

establish a maximum permissible level for residues of Cry1B.868 and Cry1Da_7 proteins.

DATES: This regulation is effective May 17, 2024. Objections and requests for hearings must be received on or before July 16, 2024, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2020–0546, is available at *https://www.regulations.gov.* Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Madison Le, Biopesticides and Pollution Prevention Division (7511M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 564–5754; email address: *BPPDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2020–0546 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before July 16, 2024. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2020–0546, by one of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

II. Background and Statutory Findings

In the **Federal Register** of December 23, 2020 (85 FR 83880) (FRL–10017–71), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 0F8839) by Bayer Crop Science LP, 800 N Lindbergh Blvd., St. Louis, Missouri 63167. The petition requested that 40 CFR part 174 be amended by establishing an exemption from the requirement of a tolerance for residues of Cry1B.868 and Cry1Da_7 proteins derived from *Bacillus thuringienisis* when used as a PIP in or on the following food and feed commodities: corn, field; corn, sweet; and corn, pop. That document referenced a summary of the petition prepared by the petitioner Bayer U.S.—Crop Science, which is available in the docket at *https://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Final Rule

A. EPA's Safety Determination

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . . '' Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider ''available information concerning the cumulative effects of a particular pesticide's residues'' and ''other substances that have a common mechanism of toxicity.''

EPA evaluated the available toxicity and exposure data on Cry1B.868 and Cry1Da_7 proteins and considered their validity, completeness, and reliability, as well as the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. A summary of the data upon which EPA relied and its risk assessment based on those data can be found within the document entitled ''Review of the Application for a FIFRA Section 3 Seed Increase Registration of MON 95379 Corn Expressing Transgenic Insecticidal Plant-Incorporated Protectants *Bacillus thuringiensis* Cry1B.868 and Cry1Da_7 Proteins and associated FFDCA Petition to Establish a Permanent Exemption from the Requirement of a Tolerance for Residues

of Cry1B.868 and Cry1Da_7 Proteins when used as Plant-Incorporated Protectants in Food and Feed Commodities of Corn'' (hereafter Human Health Risk Assessment). This document, as well as other relevant information, is available in the docket for this action EPA–HQ–OPP–2020–0546.

Cry1Da_7 and Cry1B.868 are modified proteins derived from the bacterium *Bacillus thuringiensis* (*Bt*) and are active against lepidopteran pests of corn. Available data demonstrated that, with regard to humans, Cry1B.868 and Cry1Da_7 proteins are not toxic or allergenic via any route of exposure. The most likely route of exposure is dietary, via products produced from corn expressing the Cry1B.868 and Cry1Da_7 proteins. Oral exposure from ingestion of drinking water is unlikely because the Cry1Da_7 and Cry1B.868 proteins are present at very low levels within the plant cells and the amounts likely to enter the water column from leaves, pollen or plant detritus are low. Further, if Cry1Da_7 and Cry1B.868 proteins do enter the water column, they are expected to degrade rapidly through natural processes. Although there may be dietary exposure to residues of Cry1B.868 and Cry1Da_7 proteins, such exposure presents no concern for adverse effects. Submitted data show that the Cry1B.868 and Cry1Da_7 proteins are not toxic via the oral route of exposure. Likewise, the potential for allergenicity is low because: (1) bioinformatic analysis indicates little similarity between Cry1B.868 and Cry1Da_7 proteins and known allergens; (2) Cry1B.868 and Cry1Da_7 proteins degrade rapidly when digested or exposed to heat; and (3) Cry1B.868 and Cry1Da_7 proteins are not glycosylated, which further reduces their allergenicity potential. Glycosylation is an enzymatic post-translational process in which carbohydrates (glycans) link to proteins, creating structures which could lead to an immune response in humans. In addition, pesticidal applications of *Bt* and its insecticidal proteins, including PIPs, have been safely used as commercial biological pesticides for over 50 years. The domain structure and the mode-of-action for Cry1B.868 and Cry1Da_7 proteins are similar to other *Bt* Cry insecticidal proteins that have been safely used in agriculture.

Non-dietary occupational or residential exposure via inhalation is not likely since Cry1B.868 and Cry1Da_7 proteins are contained within plant cells, and corn pollen is not respirable nor is it present in commercial corn products. Exposure via the skin may be possible via contact with corn products which might have been processed in a way that disrupts cellular structure. However, naturally occurring proteases are likely to degrade proteins in contact with the skin and, as described above, the Cry1B.868 and Cry1Da_7 proteins have little or no potential toxicity or allergenicity. These findings are discussed in more detail in the Human Health Risk Assessment.

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' No risk of cumulative toxicity or effects from Cry1B.868 and Cry1Da_7 proteins have been identified as no toxicity or allergenicity has been shown for these proteins in the submitted studies. Therefore, EPA has concluded that Cry1B.868 and Cry1Da_7 proteins do not have a common mechanism of toxicity with other substances.

Although FFDCA section 408(b)(2)(C) provides for an additional tenfold margin of safety for infants and children in the case of threshold effects, EPA has determined that there are no such effects due to the lack of toxicity of Cry1B.868 and Cry1Da_7 proteins. As a result, an additional margin of safety for the protection of infants and children is unnecessary.

Based upon its evaluation described above and in the Human Health Risk Assessment, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of Cry1B.868 and Cry1Da_7 proteins. Therefore, an exemption from the requirement of a tolerance is established for residues of Cry1B.868 and Cry1Da_7 proteins in or on the food and feed commodities of corn: corn, field; corn, sweet; and corn, pop when used as a plant-incorporated protectant in corn.

B. Analytical Enforcement Methodology

EPA has determined that an analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation. Nonetheless, Enzyme-Linked Immunosorbent Assays (ELISA) were submitted for the detection of Cry1B.868 and Cry1Da_7 proteins. These assays have been demonstrated to reliably detect the levels of the Cry1B.868 and Cry1Da_7 proteins in the tissues of corn.

IV. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption from the requirement of a tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the National Government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), do not apply to this action. In

addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

V. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 174

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 10, 2024.

Edward Messina,

Director, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 174—PROCEDURES AND REQUIREMENTS FOR PLANT–INCORPORATED PROTECTANTS

■ 1. The authority citation for part 174 continues to read as follows:

Authority: 7 U.S.C. 136–136y; 21 U.S.C. 321(q), 346a and 371.

■ 2. Add § 174.546 to subpart W to read as follows:

§ 174.546 Bacillus thuringensis Cry1B.868 and Cry1Da_7 proteins; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringensis* Cry1B.868 and Cry1Da_7 proteins in or on the food and feed commodities of corn: corn, field; corn, sweet; and corn, pop are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in corn.

[FR Doc. 2024–10848 Filed 5–16–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 372

[EPA–HQ–OPPT–2024–0044; FRL–9427.1–01–OCSPP]

RIN 2070–AL04

Implementing Statutory Addition of Certain Per- and Polyfluoroalkyl Substances (PFAS) to the Toxics Release Inventory Beginning With Reporting Year 2024

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is updating the list of chemicals subject to toxic chemical release reporting under the Emergency Planning and Community Right-to-Know Act (EPCRA) and the Pollution Prevention Act (PPA). Specifically, this action updates the regulations to identify seven per- and polyfluoroalkyl substances (PFAS) that must be reported pursuant to the National Defense Authorization Act for Fiscal Year 2020 (FY2020 NDAA) enacted on December 20, 2019. As this action is being taken to conform the regulations to a Congressional legislative mandate, notice and comment rulemaking is unnecessary.

DATES: This final rule is effective June 17, 2024.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2024–0044, is available at *https://www.regulations.gov.* Additional instructions on 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: Harichandana Karne, Data Gathering, Management and Policy Division (7406M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–0595; email address: *karne.harichandana@epa.gov.*

For general information: The Emergency Planning and Community Right-to-Know Act Hotline; telephone numbers: toll free at (800) 424–9346 (select menu option 3) or (703) 348–5070 in the Washington, DC Area and International; or go to *https://www.epa.gov/home/epa-hotlines.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture, process, or otherwise use any of the PFAS listed in this rule, including but not limited to entities identified with the following North American Industry Classification System (NAICS) codes.

- Facilities included in the following NAICS manufacturing codes (corresponding to Standard Industrial Classification (SIC) codes 20 through 39): 311*, 312*, 313*, 314*, 315*, 316, 321, 322, 323*, 324, 325*, 326*, 327*, 331, 332, 333, 334*, 335*, 336, 337*, 339*, 111998*, 113310, 211130*, 212323*, 212390*, 488390*, 512230*, 512250*, 5131*, 516210*, 519290*, 541713*, 541715* or 811490*. *Exceptions and/or limitations exist for these NAICS codes.
- Facilities included in the following NAICS codes (corresponding to SIC codes other than SIC codes 20 through 39): 211130* (corresponds to SIC code 1321, Natural Gas Liquids, and SIC 2819, Industrial Inorganic Chemicals, Not Elsewhere Classified); or 212114, 212115, 212220, 212230, 212290*; or 2211*, 221210*, 221330 (limited to facilities that combust coal and/or oil for the purpose of generating power for distribution in commerce) (corresponds to SIC codes 4911, 4931, and 4939, Electric Utilities); or 424690, 424710 (corresponds to SIC code 5171, Petroleum Bulk Terminals and Plants); 425120 (limited to facilities previously classified in SIC code 5169, Chemicals and Allied Products, Not Elsewhere Classified); or 562112 (limited to facilities primarily engaged in solvent recovery services on a contract or fee basis (previously classified under SIC code 7389, Business Services, NEC)); or 562211*, 562212*, 562213*, 562219*, 562920 (limited to facilities regulated under the Resource Conservation and Recovery Act, subtitle C, 42 U.S.C. 6921 *et seq.*) (corresponds to SIC code 4953, Refuse Systems). *Exceptions and/or limitations exist for these NAICS codes.
- Federal facilities.

A more detailed description of the types of facilities subject to reporting under EPCRA section 313 can be found at: *https://www.epa.gov/toxics-release-inventory-tri-program/tri-covered-industry-sectors.* To determine whether your facility would be affected by this action, you should carefully examine the applicability criteria in 40 CFR part 372, subpart B. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What action is the Agency taking?

EPA is codifying the addition of the seven PFAS that were added to the EPCRA section 313 list of reportable chemicals (more commonly known as the Toxics Release Inventory (TRI)) since the last conforming rule pursuant to the FY2020 NDAA (87 FR 42651, July 18, 2022 (FRL–9427–01–OCSPP)).

C. What is the Agency's authority for taking this action?

This action is issued under EPCRA section 313 (42 U.S.C. 11001 *et seq.*), section 6607 of the Pollution Prevention Act (PPA) (42 U.S.C. 13106), and section 7321 of FY2020 NDAA (Pub. L. 116–92).

II. Background

A. What is NDAA section 7321?

On December 20, 2019, the FY2020 NDAA was signed into law. Among other provisions, section 7321(c) identifies certain regulatory activities that automatically add PFAS or classes of PFAS to the EPCRA section 313 list of reportable chemicals. PFAS or classes of PFAS shall be added to the EPCRA section 313 list of reportable chemicals beginning January 1 of the calendar year after any one of the following dates:

- *Final Toxicity Value*. The date on which the Administrator finalizes a toxicity value for the PFAS or class of PFAS;
- *Significant New Use Rule*. The date on which the Administrator makes a covered determination for the PFAS or class of PFAS;
- *Addition to Existing Significant New Use Rule*. The date on which the PFAS or class of PFAS is added to a list of substances covered by a covered determination;
- *Addition as an Active Chemical Substance*. The date on which the PFAS or class of PFAS to which a covered determination applies is:

(1) Added to the list published under section 8(b)(1) of the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601 *et seq.*) and designated as an active chemical substance under TSCA section 8(b)(5)(A); or

(2) Designated as an active chemical substance under TSCA section 8(b)(5)(B) on the list published under TSCA section 8(b)(1).

The FY2020 NDAA defines ''covered determination'' as a determination made by rule under TSCA section 5(a)(2) that a use of a PFAS or class of PFAS is a significant new use (except such a determination made in connection with a determination described in TSCA sections 5(a)(3)(B) or 5(a)(3)(C)).

Under FY2020 NDAA section 7321(e), EPA must review confidential business information (CBI) claims before PFAS are added to the list pursuant to FY2020 NDAA section 7321, subsections (b)(1), (c)(1), or (d)(3), whose identities are subject to a claim of protection from disclosure under 5 U.S.C. 552(a), pursuant to 5 U.S.C. 552(b)(4). Under the FY2020 NDAA EPA must:

- Review a claim of protection from disclosure; and
- Require that person to reassert and substantiate or re-substantiate that claim in accordance with TSCA section 14(f) (15 U.S.C. 2613(f)).

In addition, if EPA determines that the chemical identity of a PFAS or class of PFAS qualifies for protection from disclosure, EPA must include the PFAS or class of PFAS on the TRI in a manner that does not disclose the protected information.

B. What PFAS have been added to the TRI list?

EPA has reviewed the above-listed criteria and found seven chemicals that meet the requirements of this part of the FY2020 NDAA and whose identity is not claimed as CBI.

Chemical name/CASRN *	Triggering action	Effective date
Perfluorohexanoic acid (PFHxA) (307–24–4)	Final Toxicity Value (Ref. 1)	1/1/24
Perfluoropropanoic acid (PFPrA) (422–64–0)	Final Toxicity Value (Ref. 2)	1/1/24
Sodium perfluorohexanoate (2923–26–4)	Final Toxicity Value (Ref. 1)	1/1/24
Ammonium perfluorohexanoate (21615–47–4)	Final Toxicity Value (Ref. 1)	1/1/24
1,1,1-Trifluoro-N-[(trifluoromethyl)sulfonyl] methanesulfonamide (TFSI) (82113–65–3)	Final Toxicity Value (Ref. 3)	1/1/24
Lithium bis[(trifluoromethyl)sulfonyl] azanide (90076–65–6)	Final Toxicity Value (Ref. 3)	1/1/24
Betaines, dimethyl(.gamma.-.omega.-perfluoro-.gamma.-hydro-C8-18-alkyl) (2816091–53–7)	CBI Declassification (Ref. 4)	1/1/24

* CASRN means Chemical Abstracts Service Registry Number.

Under FY2020 NDAA section 7321(e), EPA must review CBI claims before PFAS whose identities are subject to a claim of protection from disclosure under 5 U.S.C. 552(a) (pursuant to 5 U.S.C. 552(b)(4)) are added to the list. The substance with the CASRN 2816091–53–7 met the criteria under FY2020 NDAA section 7321(c)(1)(A)(iii) but was subject to a claim of protection from disclosure under 5 U.S.C. 552(b)(4) at that time (*i.e.,* when the FY2020 NDAA was enacted). This substance's identity has since published on the non-confidential portion of the TSCA Inventory in 2023; therefore, pursuant to FY2020 NDAA section 7321(e) the chemical was added to the TRI list and is being codified in the regulatory list by this rulemaking.

As established by the FY2020 NDAA, the addition of these PFAS to the EPCRA section 313 list of reportable chemicals is effective January 1 of the calendar year following any of the dates identified in FY2020 NDAA section 7321(c)(1)(A). Accordingly, these seven PFAS are reportable beginning with the 2024 reporting year (*i.e.,* reports due July 1, 2025), and EPA is issuing this final rule to amend the EPCRA section 313 list of reportable chemicals in 40 CFR 372.65 to include the seven non-CBI PFAS added pursuant to the FY2020 NDAA.

Note that pursuant to EPA's final rule, entitled ''Changes to Reporting Requirements for Per- and Polyfluoroalkyl Substances and to Supplier Notifications for Chemicals of Special Concern; Community Right-to-Know Toxic Chemical Release Reporting; Final Rule'' (88 FR 74360, October 31, 2023 (FRL–8741–04–OCSPP)), all PFAS added to TRI pursuant to FY2020 NDAA sections 7321(b) and (c), are designated as chemicals of special concern (40 CFR 372.28), which also applies to the seven PFAS identified in this rulemaking. Chemicals of special concern are excluded from the *de minimis* exemption, may not be reported on a Form A (Alternate Threshold Certification Statement), and have limits related to reporting requirements. For more information on the addition of PFAS to the list of chemicals of special concern, see 40 CFR 372.280.

III. Good Cause Exception

Section 553(b)(B) of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that public notice and comment procedures are

impracticable, unnecessary, or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for making this rule final without prior proposal and opportunity for comment because such notice and opportunity for comment is unnecessary. This action is being taken to comply with a mandate in an Act of Congress, where Congress identified actions that automatically add these chemicals to the TRI. Thus, EPA has no discretion as to the outcome of this rule, which merely aligns the regulations with the self-effectuating changes provided by the FY2020 NDAA.

IV. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not itself physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Toxicological Review of Perfluorohexanoic Acid (PFHxA) and Related Salts (Final Report, 2023). EPA/635/R–23/027F. 2023.
2. EPA. ORD Human Health Toxicity Value for Perfluoropropanoic Acid (CASRN 422–64–0 | DTXSID8059970). EPA/600/R–22–042F. 2023.
3. EPA. ORD Human Health Toxicity Value for Lithium bis [(trifluoromethyl)sulfonyl]azanide (HQ–115) (CASRN 90076–65–6 | DTXSID8044468). EPA/600/R–22/195F. 2023.
4. EPA. Non-CBI TSCA Inventory, February 2024.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This action is not a significant regulatory action as defined in Executive Order 12866 (58 FR 51735, October 4, 1993), as amended by Executive Order 14094 (88 FR 21879, April 11, 2023), and was therefore not subject to review under Executive Order 12866.

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA, 44 U.S.C. 3501 *et seq.* Burden is defined in 5 CFR 1320.3(b). The Office of Management and Budget (OMB) has previously approved the information collection activities contained in the existing regulations and assigned OMB control numbers 2070–0212 and 2050–0078.

Currently, the facilities subject to the reporting requirements under EPCRA section 313 and PPA section 6607 must use EPA Toxic Chemicals Release Inventory Form R (EPA Form 9350–1). The seven newly added PFAS are subject to the same reporting requirements as other chemicals of special concern and are excluded from certain burden-reduction reporting options (*i.e.,* the *de minimis* exemption and the option to use Form A, range reporting). The Form R must be completed if a facility manufactures, processes, or otherwise uses any listed chemical above threshold quantities and meets certain other criteria.

Respondents may designate the specific chemical identity of a substance as a trade secret pursuant to EPCRA section 322 (42 U.S.C. 11042) and 40 CFR part 350. OMB has approved the reporting and recordkeeping requirements related to Form R, supplier notification, and petitions under OMB Control No. 2070–0212 (EPA Information Collection Request (ICR) No. 2613.04) and those related to trade secret designations under OMB Control No. 2050–0078 (EPA ICR No. 1428.12).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers relevant to EPA's regulations in 40 CFR are listed in 40 CFR part 9 and displayed on the information collection instruments (*e.g.,* forms, instructions).

C. Regulatory Flexibility Act (RFA)

This action is not subject to the RFA, 5 U.S.C. 601 *et seq.* The RFA applies only to rules subject to notice and comment rulemaking requirements under the APA, 5 U.S.C. 553, or any other statute. As discussed in Unit III., this rule is not subject to notice and comment requirements because the Agency has invoked the APA ''good cause'' exception under 5 U.S.C. 553(b).

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any State, local, or Tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). because it will not have substantial direct effects on Tribal governments, on the relationship between the Federal Government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. It does not have substantial direct effects on Tribal governments because EPA does not anticipate that reporting of the PFAS added to the TRI list in this action will be conducted by Tribes, so this rulemaking is not expected to impose substantial direct compliance costs on Tribal governments.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it does not concern an environmental health or safety risk. Since this action does not concern human health, EPA's 2021 Policy on Children's Health also does not apply.

Although this action does not concern an environmental health or safety risk, this reporting rule will aid in collecting information regarding PFAS. This rule will be of use in identifying releases of PFAS to which children may be exposed. EPA believes that the information obtained as a result of this action could also be used by the public, government agencies and others to identify potential problems, set priorities, and take appropriate steps to reduce any potential human health or environmental risks related to PFAS, including those that may disproportionately affect children.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a significant energy action as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have any adverse effect on the supply, distribution or use of energy.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards. As such, NTTAA section 12(d), 15 U.S.C. 272, does not apply to this action.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

Executive Order 12898 (59 FR 7629, February 16, 1994) directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice a part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations (people of color) and low-income populations.

EPA believes that this type of action does not concern human health or environmental conditions and therefore cannot be evaluated with respect to potentially disproportionate and adverse effects on communities with environmental justice concerns. This action involves additions to reporting requirements that will not affect the level of protection provided to human health or the environment.

Although this action does not concern human health or environmental conditions, EPA may identify and address environmental justice concerns through information collected under TRI. The information obtained as a result of this rulemaking will lead to a better understanding of PFAS releases, which can help inform and tailor future EPA actions regarding PFAS. For example, EPA may identify and address environmental justice concerns as a result of the new PFAS information collected under this rule. The action will also better inform communities living near facilities that report to TRI, by providing them with information about PFAS releases and waste management practices occurring in their communities. Overall, EPA believes that the information obtained as a result of this action could be used by the public (including people of color, low-income populations and/or indigenous peoples) to inform their behavior as it relates to potential exposure to PFAS and by government agencies and others to identify potential problems, set priorities, and take appropriate steps to reduce any potential human health or environmental risks from PFAS.

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.,* and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 372

Environmental protection, Community right-to-know, Reporting and recordkeeping requirements, Toxic chemicals.

Dated: May 9, 2024.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 372—TOXIC CHEMICAL RELEASE REPORTING: COMMUNITY RIGHT-TO-KNOW

■ 1. The authority citation for part 372 continues to read as follows:

Authority: 42 U.S.C. 11023 and 11048.

■ 2. Amend § 372.65:

■ a. In table 4 to paragraph (d), by:

■ i. Revising the heading to the second column;

■ ii. Adding in alphabetical order entries for ''Ammonium perfluorohexanoate''; ''Betaines, dimethyl(γ-ω-perfluoro-γ-hydro-C8-18-alkyl)''; ''Lithium bis[(trifluoromethyl)sulfonyl] azanide''; ''Perfluorohexanoic acid''; ''Perfluoropropanoic acid''; ''Sodium perfluorohexanoate''; and ''1,1,1-Trifluoro-N-[(trifluoromethyl)sulfonyl] methanesulfonamide''; and

■ iii. Adding a note to the end of the table.

■ b. In table 5 to paragraph (e), by:

■ i. Revising the heading to the first column;

■ ii. Adding in numerical order entries for ''307–24–4''; ''422–64–0''; ''2923–26–4''; ''21615–47–4''; ''82113–65–3''; ''90076–65–6''; and ''2816091–53–7''; and

■ iii. Adding a note to the end of the table.

The additions and revisions read as follows:

§ 372.65 Chemicals and chemical categories to which this part applies.

* * * * *

(d) * * *

TABLE 4 TO PARAGRAPH (d)

Chemical name	CASRN [1]	Effective date
* * * * *	*	*
Ammonium perfluorohexanoate	21615–47–4	1/1/24
* * * * *	*	*
Betaines, dimethyl(γ-ω-perfluoro-γ-hydro-C8-18-alkyl)	2816091–53–7	1/1/24
* * * * *	*	*
Lithium bis[(trifluoromethyl)sulfonyl] azanide	90076–65–6	1/1/24
* * * * *	*	*
Perfluorohexanoic acid	307–24–4	1/1/24
* * * * *	*	*
Perfluoropropanoic acid	422–64–0	1/1/24

TABLE 4 TO PARAGRAPH (d)—Continued

Chemical name	CASRN [1]	Effective date
* * * * * * *		
Sodium perfluorohexanoate	2923–26–4	1/1/24
* * * * * * *		
1,1,1-Trifluoro-N-[(trifluoromethyl)sulfonyl] methanesulfonamide	82113–65–3	1/1/24

[1] CASRN means Chemical Abstracts Service Registry Number.

(e) * * *

TABLE 5 TO PARAGRAPH (e)

CASRN [1]	Chemical name	Effective date
307–24–4	Perfluorohexanoic acid	1/1/24
* * * * * * *		
422–64–0	Perfluoropropanoic acid	1/1/24
* * * * * * *		
2923–26–4	Sodium perfluorohexanoate	1/1/24
* * * * * * *		
21615–47–4	Ammonium perfluorohexanoate	1/1/24
* * * * * * *		
82113–65–3	1,1,1-Trifluoro-N-[(trifluoromethyl)sulfonyl] methanesulfonamide	1/1/24
* * * * * * *		
90076–65–6	Lithium bis[(trifluoromethyl)sulfonyl] azanide	1/1/24
* * * * * * *		
2816091–53–7	Betaines, dimethyl(γ-ω-perfluoro-γ-hydro-C8-18-alkyl)	1/1/24

[1] CASRN means Chemical Abstracts Service Registry Number.

[FR Doc. 2024–10568 Filed 5–16–24; 8:45 am]

BILLING CODE 6560–50–P

Proposed Rules

Federal Register
Vol. 89, No. 97
Friday, May 17, 2024

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–1304; Project Identifier MCAI–2023–01134–T]

RIN 2120–AA64

Airworthiness Directives; Embraer S.A. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2020–25–07, which applies to certain Embraer S.A. Model EMB–550 and EMB–545 airplanes. AD 2020–25–07 requires repetitive inspections of the flight deck side windows for any cracking or delamination, corrective action if necessary, and eventual replacement of the windows. Since the FAA issued AD 2020–25–07, additional part numbers were added to the installation prohibition list. This proposed AD would continue to require the actions in AD 2020–25–07, expand the list of affected parts, and prohibit the installation of affected parts, as specified in an Agência Nacional de Aviação Civil (ANAC) AD, which is proposed for incorporation by reference (IBR). 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 July 1, 2024.

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 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.

AD Docket: You may examine the AD docket at regulations.gov under Docket No. FAA–2024–1304; 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.

Material Incorporated by Reference:

- For ANAC material, contact National Civil Aviation Agency (ANAC), Aeronautical Products Certification Branch (GGCP), Rua Dr. Orlando Feirabend Filho, 230—Centro Empresarial Aquarius—Torre B—Andares 14 a 18, Parque Residencial Aquarius, CEP 12.246–190—São José dos Campos—SP, Brazil; telephone 55 (12) 3203–6600; email *pac@anac.gov.br;* website *anac.gov.br/en/.* You may find this material on the ANAC website *sistemas.anac.gov.br/certificacao/DA/DAE.asp.* It is also available at *regulations.gov* under Docket No. FAA–2024–1304.
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th Street, Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

FOR FURTHER INFORMATION CONTACT: Hassan Ibrahim, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3653; email *hassan.m.ibrahim@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–2024–1304; Project Identifier MCAI–2023–01134–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 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 Hassan Ibrahim, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3653; email *hassan.m.ibrahim@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2020–25–07, Amendment 39–21349 (85 FR 81385, December 16, 2020) (AD 2020–25–07), for certain Embraer S.A. Model EMB–550 and EMB–545 airplanes. AD 2020–25–07 was prompted by an MCAI originated by ANAC, which is the aviation authority for Brazil. ANAC issued AD 2020–04–01R01, effective May 22, 2020, to correct an unsafe condition.

AD 2020–25–07 requires repetitive inspections of the flight deck side windows for any cracking or delamination, corrective action if necessary, and eventual replacement of the windows. The FAA issued AD

2020–25–07 to address cracks and delamination, which could cause the flight deck side windows to fail and lead to an in-flight depressurization event.

Actions Since AD 2020–25–07 Was Issued

Since the FAA issued AD 2020–25–07, ANAC superseded ANAC AD 2020–04–01R01, effective May 22, 2020, and issued ANAC AD 2020–04–01R02, effective November 2, 2023 (ANAC AD 2020–04–01R02) (also referred to as the MCAI), to correct an unsafe condition for certain Embraer S.A. Model EMB–550 and EMB–545 airplanes. The MCAI states that part number (P/N) NP–200402–7 and P/N NP–200402–8, made mandatory by the previous revisions of the MCAI, have not had the expected effect on the fleet as premature cracks in the outer layer of windows with P/N NP–200402–7 and P/N NP–200402–8 have been found. These cracks may be undetected, and the inner layer may be subjected to unpredicted loads for several flights, which could result in window failure and subsequent in-flight depressurization events.

The FAA is proposing this AD to address the unsafe condition on these products. You may examine the MCAI in the AD docket at regulations.gov under Docket No. FAA–2024–1304.

Explanation of Retained Requirements

Although this proposed AD does not explicitly restate the requirements of AD 2020–25–07, this proposed AD would retain all of the requirements of AD 2020–25–07. Those requirements are referenced in ANAC AD 2020–04–01R02, which, in turn, is referenced in paragraph (g) of this proposed AD.

Related Service Information Under 1 CFR Part 51

ANAC AD 2020–04–01R02 specifies procedures for initial and repetitive detailed inspections of the left-hand cockpit side window P/N NP–200402–1 or P/N NP–200402–5 and right-hand cockpit side window P/N NP–200402–2 or P/N NP–200402–6 to detect cracks, delamination, or any other damage (such as scratches, chipping, erosion, and crazing), and replacement of the windows with a new window P/N NP–200402–9 or P/N NP–200402–10, as applicable. ANAC AD 2020–04–01R02 also prohibits the installation of flight deck side windows with P/N NP–200402–1, P/N NP–200402–2, P/N NP–200402–5, P/N NP–200402–6, P/N NP–200402–7, and P/N NP–200402–8, on any airplane.

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 this 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 ANAC AD 2020–04–01R02 described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD. This proposed AD would also prohibit the installation of affected parts.

Additional Proposed Changes in This NPRM

In the ''Costs of Compliance'' section, AD 2020–25–07 stated an incorrect estimated costs for required actions. This NPRM corrects the estimated cost of the required action of inspecting the windows from 10 work-hours to 1 work-hour. The on-condition actions of replacing the windows have been updated to the latest cost and work-hours.

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 ANAC AD 2020–04–01R02 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with ANAC AD 2020–04–01R02 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Service information required by ANAC AD 2020–04–01R02 for compliance will be available at regulations.gov under Docket No. FAA–2024–1304 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 44 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions from AD 2020–25–07.	1 work-hour × $85 per hour = $85, per inspection cycle.	$0	$85, per inspection cycle.	$3,740, per inspection cycle.

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

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per window
15 work-hours × $85 per hour = $1,275	$21,636	$22,911

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:

■ a. Removing Airworthiness Directive 2020–25–07, Amendment 39–21349 (85 FR 81385, December 16, 2020); and

■ b. Adding the following new airworthiness directive:

Embraer S.A.: Docket No. FAA–2024–1304; Project Identifier MCAI–2023–01134–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by July 1, 2024.

(b) Affected ADs

This AD replaces AD 2020–25–07, Amendment 39–21349 (85 FR 81385, December 16, 2020) (AD 2020–25–07).

(c) Applicability

This AD applies to Embraer S.A. Model EMB–550 and EMB–545 airplanes, certificated in any category, as identified in Agência Nacional de Aviação Civil (ANAC) AD 2020–04–01R02, effective November 2, 2023 (ANAC AD 2020–04–01R02).

(d) Subject

Air Transport Association (ATA) of America Code 56, Windows.

(e) Unsafe Condition

This AD was prompted by reports of cracks, delamination, and failure of the flight deck side windows during certification fatigue tests. The FAA is issuing this AD to address such cracks and delamination, and any other damage of the flight deck side windows. The unsafe condition, if not addressed, could result in flight deck side windows to fail and lead to an in-flight depressurization event.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, ANAC AD 2020–04–01R02.

(h) Exceptions to ANAC AD 2020–04–01R02

(1) Where ANAC AD 2020–04–01R02 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where paragraph (b)(1) of ANAC AD 2020–04–01R02 refers to April 17, 2020 (the effective date of the original issue of ANAC AD 2020–04–01), this AD requires using January 21, 2021 (the effective date of AD 2020–25–07).

(3) Where paragraph (b)(1)(iii) of ANAC AD 2020–04–01R02 specifies ''In case of no crack, delamination, or any other damage, no action is required at this time,'' this AD requires replacing that text with ''In the case of no crack, delamination, or any other damage found during the inspection specified in paragraph (b)(1) of ANAC AD 2020–04–01R02, no further action is required by this AD until the next inspection interval.''

(4) Where paragraph (b)(2) of ANAC AD 2020–04–01R02 refers to the compliance time of the repetitive inspections, ''at each 750 Flight Hours (FH),'' this AD requires replacing that text with ''at intervals not to exceed 750 flight hours.''

(5) Where paragraph (c) of ANAC AD 2020–04–01R02 refers to the compliance time for the replacement of the flight deck side windows as, ''before the airplane logs 3,400 Flight Cycles Since New (FCSN),'' this AD requires replacing that text with ''before the airplane logs 3,400 FCSN, or within 50 flight cycles, whichever occurs later.''

(6) Replacement of the flight deck side windows as specified in paragraph (c) of ANAC AD 2020–04–01R02 terminates the repetitive inspections for the flight deck side windows specified in paragraph (b)(2) of ANAC AD 2020–04–01R02.

(7) This AD does not adopt paragraph (e) of ANAC AD 2020–04–01R02.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, 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 manager of the International Validation Branch, mail it to the address identified in paragraph (j) 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, International Validation Branch, FAA; or ANAC; or ANAC's authorized Designee. If approved by the ANAC Designee, the approval must include the Designee's authorized signature.

(j) Additional Information

For more information about this AD, contact Hassan Ibrahim, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3653; email *hassan.m.ibrahim@faa.gov.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Agência Nacional de Aviação Civil (ANAC) AD 2020–04–01R02, effective November 2, 2023.

(ii) [Reserved]

(3) For ANAC AD 2020–04–01R02, contact ANAC, Aeronautical Products Certification Branch (GGCP), Rua Dr. Orlando Feirabend Filho, 230—Centro Empresarial Aquarius—Torre B—Andares 14 a 18, Parque Residencial Aquarius, CEP 12.246–190—São José dos Campos—SP, Brazil; telephone 55 (12) 3203–6600; email *pac@anac.gov.br;* website *anac.gov.br/en/.* You may find this ANAC AD on the ANAC website at *sistemas.anac.gov.br/certificacao/DA/DAE.asp.*

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

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locationsoremailfr.inspection@nara.gov.*

Issued on May 8, 2024.

James D. Foltz,

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

[FR Doc. 2024–10508 Filed 5–16–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–1300; Project Identifier MCAI–2024–00081–T]

RIN 2120–AA64

Airworthiness Directives; Dassault Aviation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2023–25–07, which applies to all Dassault Aviation Model MYSTERE–FALCON 900 airplanes. AD 2023–25–07 requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. Since the FAA issued AD 2023–25–07, the FAA has determined that new or more restrictive airworthiness limitations are necessary. This proposed AD would continue to require certain actions in AD 2023–25–07 and would require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference (IBR). 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 July 1, 2024.

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 *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.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–1300; 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.

Material Incorporated by Reference:

- For material that is proposed for IBR in this NPRM, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2024–1300.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 206–231–3226; email *tom.rodriguez@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–2024–1300; Project Identifier MCAI–2024–00081–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 *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 Tom Rodriguez, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 206–231–3226; email *tom.rodriguez@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2023–25–07, Amendment 39–22634 (89 FR 244, January 3, 2024; corrected January 18, 2024 (89 FR 3342); corrected January 26, 2024 (89 FR 5088)) (AD 2023–25–07), for all Dassault Aviation Model MYSTERE–FALCON 900 airplanes. AD 2023–25–07 was prompted by an MCAI originated by EASA, which is the Technical Agent for the Member States of the European Union. EASA issued AD 2023–0046, dated March 2, 2023 (EASA AD 2023–0046) (which corresponds to FAA AD 2023–25–07), to correct an unsafe condition.

AD 2023–25–07 requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. The FAA issued AD 2023–25–07 to address reduced structural integrity of the airplane.

Actions Since AD 2023–25–07 Was Issued

Since the FAA issued AD 2023–25–07, EASA superseded AD 2023–0046 and issued EASA AD 2024–0036, dated January 31, 2024 (EASA AD 2024–0036) (referred to after this as the MCAI), for all Dassault Aviation Model MYSTERE–FALCON 900 airplanes. The MCAI states that new or more restrictive airworthiness limitations have been developed.

The FAA is proposing this AD to address reduced structural integrity of the airplane. You may examine the MCAI in the AD docket at regulations.gov under Docket No. FAA–2024–1300.

Related Service Information Under 1 CFR Part 51

The FAA reviewed EASA AD 2024–0036. This service information specifies new or more restrictive airworthiness limitations for airplane structures and safe life limits.

This proposed AD would also require EASA AD 2023–0046, which the Director of the Federal Register approved for incorporation by reference as of February 7, 2024 (89 FR 244, January 3, 2024).

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 **ADDRESSES**.

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 this 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 retain certain requirements of AD 2023–25–07. This proposed AD would also require revising the existing maintenance or inspection program, as applicable, to incorporate additional new or more restrictive airworthiness limitations, which are specified in EASA AD 2024–0036 already described, as proposed for incorporation by reference. Any differences with EASA AD 2024–0036 are identified as exceptions in the regulatory text of this AD.

This proposed AD would require revisions to certain operator maintenance documents to include new actions (*e.g.,* inspections). Compliance with these actions is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this proposed AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance (AMOC) according to paragraph (m)(1) 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 retain the IBR of EASA AD 2023–0046 and incorporate EASA AD 2024–0036 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2024–0036 and EASA AD 2023–0046 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 2024–0036 or EASA AD 2023–0046 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 2024–0036 or EASA AD 2023–0046. Service information required by EASA AD 2024–0036 and EASA AD 2023–0046 for compliance will be available at *regulations.gov* by searching for and locating Docket No. FAA–2024–1300 after the FAA final rule is published.

Airworthiness Limitation ADs Using the New Process

The FAA's process of incorporating by reference MCAI ADs as the primary source of information for compliance with corresponding FAA ADs has been limited to certain MCAI ADs (primarily those with service bulletins as the primary source of information for accomplishing the actions required by the FAA AD). However, the FAA is now expanding the process to include MCAI ADs that require a change to airworthiness limitation documents, such as airworthiness limitation sections.

For these ADs that incorporate by reference an MCAI AD that changes airworthiness limitations, the FAA requirements are unchanged. Operators must revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in the new airworthiness limitation document. The airworthiness limitations must be followed according to 14 CFR 91.403(c) and 91.409(e).

The previous format of the airworthiness limitation ADs included a paragraph that specified that no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions and intervals are approved as an AMOC in accordance with the procedures specified in the AMOCs paragraph under ''Additional AD Provisions.'' This new format includes a ''New Provisions for Alternative Actions and Intervals'' paragraph that does not specifically refer to AMOCs, but operators may still request an AMOC to use an alternative action or interval.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 151 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

The FAA estimates the total cost per operator for the retained actions from AD 2023–25–07 to be $7,650 (90 work-hours × $85 per work-hour).

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

The FAA estimates the total cost per operator for the new proposed actions to be $7,650 (90 work-hours × $85 per work-hour).

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:

■ a. Removing Airworthiness Directive (AD) 2023–25–07, Amendment 39–22634 (89 FR 244, January 3, 2024; corrected January 18, 2024 (89 FR 3342); corrected January 26, 2024 (89 FR 5088)); and

■ b. Adding the following new AD:

Dassault Aviation: Docket No. FAA–2024–1300; Project Identifier MCAI–2024–00081–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by July 1, 2024.

(b) Affected ADs

This AD replaces AD 2023–25–07, Amendment 39–22634 (89 FR 244, January 3, 2024; corrected January 18, 2024 (89 FR 3342); corrected January 26, 2024 (89 FR 5088)) (AD 2023–25–07).

(c) Applicability

This AD applies to all Dassault Aviation Model MYSTERE–FALCON 900 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Unsafe Condition

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address reduced structural integrity of the airplane.

(f) Compliance

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

(g) Retained Revision of the Existing Maintenance or Inspection Program, With a New Exception

This paragraph restates the requirements of paragraph (j) of AD 2023–25–07, with a new exception. Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2023–0046, dated March 2, 2023 (EASA AD 2023–0046). Accomplishing the revision of the existing maintenance or inspection program required by paragraph (j) of this AD terminates the requirements of this paragraph.

(h) Retained Exceptions to EASA AD 2023–0046, With No Changes

This paragraph restates the exceptions specified in paragraph (k) of AD 2023–25–07, with no changes.

(1) This AD does not adopt the requirements specified in paragraphs (1) and (2) of EASA AD 2023–0046.

(2) Paragraph (3) of EASA AD 2023–0046 specifies revising ''the approved AMP'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after February 7, 2024 (the effective date of AD 2023–25–07).

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2023–0046 is at the applicable ''limitations'' and ''associated thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2023–0046, or within 90 days after February 7, 2024 (the effective date of AD 2023–25–07), whichever occurs later.

(4) This AD does not adopt the provisions specified in paragraphs (4) and (5) of EASA AD 2023–0046.

(5) This AD does not adopt the ''Remarks'' section of EASA AD 2023–0046.

(i) Retained Restrictions on Alternative Actions or Intervals, With a New Exception

This paragraph restates the requirements of paragraph (l) of AD 2023–25–07, with a new exception. Except as required by paragraph (j) of this AD, after the maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2023–0046.

(j) New Revision of the Existing Maintenance or Inspection Program

Except as specified in paragraph (k) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2024–0036, dated January 31, 2024 (EASA AD 2024–0036). Accomplishing the revision of the existing maintenance or inspection program required by this paragraph terminates the requirements of paragraph (g) of this AD.

(k) Exceptions to EASA AD 2024–0036

(1) This AD does not adopt the requirements specified in paragraphs (1) and (2) of EASA AD 2024–0036.

(2) Paragraph (3) of EASA AD 2024–0036 specifies revising ''the approved AMP'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2024–0036 is at the applicable ''limitations'' and ''associated thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2024–0036, or within 90 days after the effective date of this AD, whichever occurs later.

(4) This AD does not adopt the provisions specified in paragraphs (4) and (5) of EASA AD 2024–0036.

(5) This AD does not adopt the ''Remarks'' section of EASA AD 2024–0036.

(l) New Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (j) of this AD, no alternative actions (*e.g.,* inspections) or intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2024–0036.

(m) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, 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 manager of the International Validation Branch, mail it to the address identified in paragraph (n) 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, International Validation Branch, FAA; or EASA; or Dassault Aviation's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(n) Additional Information

For more information about this AD, contact Tom Rodriguez, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 206–231–3226; email *tom.rodriguez@faa.gov.*

(o) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(3) The following service information was approved for IBR on [DATE 35 DAYS AFTER PUBLICATION OF THE FINAL RULE].

(i) European Union Aviation Safety Agency (EASA) AD 2024–0036, dated January 31, 2024.

(ii) [Reserved]

(4) The following service information was approved for IBR on February 7, 2024 (89 FR 244, January 3, 2024; corrected January 18, 2024 (89 FR 3342); corrected January 26, 2024 (89 FR 5088)).

(i) EASA AD 2023–0046, dated March 2, 2023.

(ii) [Reserved]

(5) For EASA ADs 2023–0046 and 2024–0036, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find these EASA ADs on the EASA website at *ad.easa.europa.eu.*

(6) 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.

(7) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

Issued on May 6, 2024.

James D. Foltz,

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

[FR Doc. 2024–10210 Filed 5–16–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–1299; Project Identifier MCAI–2023–00237–A]

RIN 2120–AA64

Airworthiness Directives; Britten-Norman Aerospace Ltd. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Britten-Norman Aerospace Ltd. Model BN–2, BN–2A, BN–2A–2, BN–2A–3, BN–2A–6, BN–2A–8, BN–2A–9, BN–2A–20, BN–2A–21, BN–2A–26, BN–2A–27, BN–2B–20, BN–2B–21, BN–2B–26, BN–2B–27, BN–2T, BN2T–4R, and BN2T–4S airplanes; and Model BN2A MK. III, BN2A MK. III–2, and BN2A MK. III–3 airplanes. This proposed AD was prompted by the determination that in order to ensure the continued structural integrity of certain landing gear and associated components, it is necessary to require removal of these components from service prior to exceeding established fatigue lives. This proposed AD would require determining the number of landings on affected main landing gears (MLGs), nose landing gears (NLGs), and associated components; removing from service any part that has reached or exceeded the established fatigue life and installing a replacement part; and prohibiting the installation of any affected part unless the number of landings for that part is below the established fatigue life. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this NPRM by July 1, 2024.

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 *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.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–1299; 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.

Material Incorporated by Reference:

- For service information, contact Britten-Norman Aerospace Ltd., Bembridge Airport, Bembridge, Isle of Wight, UK, PO35 5PR; phone: +44 20 3371 4000; email: *customer.support@britten-norman.com;* website: *britten-norman.com/approvals-technical-publications.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110.

FOR FURTHER INFORMATION CONTACT: Penelope Trease, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (303) 342–1094; email: *penelope.trease@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–2024–1299; Project Identifier MCAI–2023–00237–A'' 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 *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 Penelope Trease, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The Civil Aviation Authority (CAA), which is the airworthiness authority for the United Kingdom (UK), issued AD G–2023–0001, dated February 8, 2023 (also referred to as the MCAI), to correct an unsafe condition on Britten-Norman Aircraft Ltd. (now Britten-Norman Aerospace Ltd.) Model BN2 series Islander (BN2, BN2A, A–2, A–3, A–6, A–8, –9, –20, –21, –26, –27; BN2B–20, –21, –26, –27; BN2T; and BN2T–4R, –4S) airplanes; and Model BN2A Mark III Trislander (BN.2A MARK III, BN.2A MARK III–1, BN.2A MARK III–2, and BN.2A MARK III–3) airplanes, fitted with landing gear and associated components manufactured by Fairey Hydraulics Ltd (FHL) and Britten-Norman Aircraft (BNA). The MCAI states that to ensure the continued safe operation of the Islander's and Trislander's NLG, MLG, and associated components, the manufacturer and the UK CAA determined that affected parts exceeding the established fatigue lives must be removed from service and that installation of parts that have reached their established fatigue lives must be prohibited.

The FAA is proposing this AD to address this unsafe condition. Exceeding the established fatigue life, if not addressed, could result in failure of the structural integrity of the landing gear and associated components, which could result in damage to the airplane and injury to occupants.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–1299.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Britten-Norman Service Bulletin SB 298, Issue 3, dated July 7, 2023. This service information provides procedures for identifying the affected MLGs, NLGs, and associated components that need to have the number of landings tracked and provides the associated fatigue life. This service information also specifies to remove from service any affected part that exceeds the specified fatigue life.

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

FAA's Determination

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI and service information referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in the service information already described. This proposed AD would also prohibit the installation of a MLG, NLG, or associated component unless it is a part eligible for installation.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 87 airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Determine the number of landings accumulated on affected MLGs, NLGs, and associated components.	1 work-hour × $85 per hour = $85	$0	$85	$7,395.
Replace MLG	16 work-hours × $85 per hour = $1,360	30,000	$31,360	$2,728,320.
Replace NLG	16 work-hours × $85 per hour = $1,360	35,000	$36,360	$3,163,320.
Replace associated components	Up to 4 work-hours × $85 per hour = $340	4,000	Up to $4,340	Up to $377,580.

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:

Britten-Norman Aerospace Ltd.: Docket No. FAA–2024–1299; Project Identifier MCAI–2023–00237–A.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by July 1, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to certain Britten-Norman Aerospace Ltd. airplanes fitted with Fairey Hydraulics Ltd or Britten-Norman Aircraft landing gear and associated landing gear components, certificated in any category, identified in paragraphs (c)(1) and (2) of this AD.

(1) Model BN–2, BN–2A, BN–2A–2, BN–2A–3, BN–2A–6, BN–2A–8, BN–2A–9, BN–2A–20, BN–2A–21, BN–2A–26, BN–2A–27, BN–2B–20, BN–2B–21, BN–2B–26, BN–2B–27, BN–2T, BN2T–4R, and BN2T–4S airplanes.

(2) Model BN2A MK. III, BN2A MK. III–2, and BN2A MK. III–3 airplanes.

(d) Subject

Joint Aircraft System Component (JASC) Code 3200, Landing Gear System.

(e) Unsafe Condition

This AD was prompted by the determination that in order to ensure the continued structural integrity of certain landing gear and associated components, it is necessary to require removal of these components from service prior to exceeding established fatigue lives. Exceeding the established fatigue life, if not addressed, could result in failure of the structural integrity of the landing gear, which could result in damage to the airplane and injury to occupants.

(f) Compliance

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

(g) Definitions

For the purposes of this AD:

(1) An ''affected part'' is a main landing gear (MLG), nose landing gear (NLG), or component identified in Table 1, 2, or 3 of Section 6 in Britten-Norman SB 298, Issue 3, dated July 7, 2023 (Britten-Norman SB 298, Issue 3).

(2) A ''part eligible for installation'' is an MLG, NLG, or component with a part that has been established to be below the associated fatigue life identified in Table 1, 2, or 3 of Section 6 in Britten-Norman SB 298, Issue 3.

(h) Required Actions

(1) Within 30 days after the effective date of this AD, determine the number of landings accumulated on the affected parts.

(2) Before accumulating the number of landings (fatigue life) associated with the applicable affected part as identified in Table 1, 2, or 3 of Section 6 in Britten-Norman SB 298, Issue 3, or within the next 30 days after the effective date of this AD, whichever occurs later, replace any affected part with a part eligible for installation.

(3) Thereafter, replace any affected part with a part eligible for installation before accumulating the fatigue life, as identified in Table 1, 2, or 3 of Section 6 in Britten-Norman SB 298, Issue 3.

(4) As of the effective date of this AD, do not install a MLG, NLG, or associated component unless it is a part eligible for installation.

(i) Alternative Methods of Compliance (AMOCs)

The Manager, 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 local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (j)(2) of this AD or email to: *9-AVS-AIR-730-AMOC@faa.gov.* If mailing information, also submit information by email. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local Flight Standards District Office/certificate holding district office.

(j) Additional Information

(1) Refer to United Kingdom (UK) Civil Aviation Authority (CAA) AD G–2023–0001, dated February 8, 2023, for related information. This UK CAA AD may be found in the AD docket at *regulations.gov* under Docket No. FAA–2024–1299.

(2) For more information about this AD, contact Penelope Trease, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (303) 342–1094; email: *penelope.trease@faa.gov.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Britten-Norman Service Bulletin SB 298, Issue 3, dated July 7, 2023.

(ii) [Reserved]

(3) For service information, contact Britten-Norman Aerospace Ltd., Bembridge Airport, Bembridge, Isle of Wight, UK, PO35 5PR; phone: +44 20 3371 4000; email: *customer.support@britten-norman.com;* website: *britten-norman.com/approvals-technical-publications.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

Issued on May 7, 2024.

James D. Foltz,

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

[FR Doc. 2024–10295 Filed 5–16–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–1301; Project Identifier AD–2024–00035–T]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain The Boeing Company Model 787–9 and 787–10 airplanes. This proposed AD was prompted by reports that some floor beam side-of-body fittings have been manufactured with an incorrect material type. This proposed AD would require replacing the incorrectly manufactured floor beam side-of-body fittings, inspecting the fuselage frame and fastener holes for damage, and repairing any damage. 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 July 1, 2024.

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 *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.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–1301; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For service information, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website *myboeingfleet.com.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2024–1301.

FOR FURTHER INFORMATION CONTACT: Joseph Hodgin, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3962; email: *Joseph.J.Hodgin@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–2024–1301; Project Identifier AD–2024–00035–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 *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 Joseph Hodgin, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3962; email: *Joseph.J.Hodgin@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA has received reports that some floor beam side-of-body fittings have been manufactured with an incorrect material type between station 1233 and station 1593. The incorrect material type is a grade 1 or 2 commercially pure unalloyed titanium, which has significantly reduced strength, fatigue, and damage-tolerance properties compared to the type design grade 5 Ti-6AI–4V material. The discrepant floor beam side-of-body fitting part numbers are installed on Model 787–9 and –10 airplanes.

This condition, if not addressed, could result in failure of the fittings. The failure of multiple adjacent fittings may lead to inability of the surrounding principal structure elements to sustain limit loads and damage to critical systems under the floor; these conditions could cause loss of control of the airplane. Additionally, in the event of an emergency landing or full certified rapid decompression, failure of multiple adjacent fittings could result in the inability of the passenger floor grid to maintain the loads and could result in serious injury or impeded egress for passengers.

FAA's Determination

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

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing Alert Requirements Bulletin B787–81205–SB530084–00 RB, Issue 001, dated December 8, 2023. This service information specifies performing an X-ray fluorescence spectrometer inspection of the floor beam side-of-body fittings between station 1233 and station 1593 to determine whether the fitting was manufactured with type design grade 5 Ti-6AI–4V material. Alternatively, operators may replace all floor beam side-of-body fittings between station 1233 and station 1593 with fittings made of the correct material without performing an X-ray fluorescence spectrometer inspection. For any floor beam side-of-body fitting that needs replacement, this service information specifies inspecting the fuselage frame and fastener holes for damage, repairing any damage, and installing a floor beam side-of-body fitting made of the correct material.

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

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in the service information already described, except for any differences identified as exceptions in the regulatory text of this proposed AD. For information on the procedures and compliance times, see this service information at *regulations.gov* under Docket No. FAA–2024–1301.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 60 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS—OPTION 1

Action	Labor cost	Parts cost	Cost per airplane	Cost on U.S. operators
X-ray fluorescence spectrometer inspection to determine material type.	77 work-hours × $85 per hour = $6,545.	$0	$6,545	Up to $392,700.

ESTIMATED COSTS—OPTION 2

Action	Labor cost	Parts cost	Cost per airplane
Replace all affected floor beam side-of-body fittings and inspect for damage.	527 work-hours × $85 per hour = $44,795	$218,250	$263,045

The FAA estimates the following costs to do any replacements that would be required based on the results of the proposed inspection. The agency has no way of determining the number of aircraft that might need this replacement:

ON-CONDITION COSTS FOR OPTION 1

Action	Labor cost	Parts cost	Cost per fitting
Replace floor beam side-of-body fitting and inspect for damage (per fitting).	18 work-hours × $85 per hour = $1,530	$8,730	$10,260

The extent of damage found during the inspection done when the fittings are replaced could vary significantly from airplane to airplane. The FAA has no way of determining how much damage may be found on each airplane, the cost to repair damaged parts on each airplane, or the number of airplanes that may require repair.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2024–1301; Project Identifier AD–2024–00035–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by July 1, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 787–9 and 787–10 airplanes, certificated in any category, as identified in Boeing Alert Requirements Bulletin B787–81205–SB530084–00 RB, Issue 001, dated December 8, 2023.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by reports that some floor beam side-of-body fittings have been manufactured with an incorrect material type between station 1233 and station 1593. The FAA is issuing this AD to address the floor beam side-of-body fittings that do not meet type design and prevent

failure of the fittings. The unsafe condition, if not addressed, could result in the inability of the surrounding principal structure elements to sustain limit loads and in damage to critical systems under the floor; these conditions could cause loss of control of the airplane. Additionally, in the event of an emergency landing or full certified rapid decompression, failure of multiple adjacent fittings could result in the inability of the passenger floor grid to maintain the loads and could result in serious injury or impeded egress for passengers.

(f) Compliance

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

(g) Required Actions

Except as specified in paragraph (h) of this AD: At the applicable times specified in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin B787–81205–SB530084–00 RB, Issue 001, dated December 8, 2023, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin B787–81205–SB530084–00 RB, Issue 001, dated December 8, 2023.

Note 1 to paragraph (g): Guidance for accomplishing the actions required by this AD can be found in Boeing Alert Service Bulletin B787–81205–SB530084–00, Issue 001, dated December 8, 2023, which is referred to in Boeing Alert Requirements Bulletin B787–81205–SB530084–00 RB, Issue 001, dated December 8, 2023.

(h) Exceptions to Service Information Specifications

(1) Where the ''Boeing Recommended Compliance Time'' column in the tables under the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin B787–81205–SB530084–00 RB, Issue 001, dated December 8, 2023, refers to ''the Issue 001 date of Requirements Bulletin B787–81205–SB530084–00 RB,'' this AD requires using the effective date of this AD.

(2) Where Boeing Alert Requirements Bulletin B787–81205–SB530084–00 RB, Issue 001, dated December 8, 2023, specifies contacting Boeing for repair instructions, this AD requires doing the repair before further flight using a method approved in accordance with the procedures in paragraph (i) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, AIR–520, Continued Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j)(1) of this AD. Information may be emailed to: *AMOC@faa.gov.*

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, AIR–520, Continued Operational Safety Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(j) Related Information

(1) For more information about this AD, contact Joseph Hodgin, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3962; email: *Joseph.J.Hodgin@faa.gov.*

(2) For service information identified in this AD that is not incorporated by reference, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website *myboeingfleet.com.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing Alert Requirements Bulletin B787–81205–SB530084–00 RB, Issue 001, dated December 8, 2023.

(ii) [Reserved]

(3) For service information, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website *myboeingfleet.com.*

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

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

Issued on May 7, 2024.

James D. Foltz,

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

[FR Doc. 2024–10299 Filed 5–16–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2024–1361; Airspace Docket No. 24–ANE–05]

RIN 2120–AA66

Revocation of Class E Airspace; Manchester, NH

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to remove Class E surface airspace for Manchester Boston Regional Airport, Manchester, NH, as the overlying Class C airspace deems the Class E surface airspace unnecessary.

DATES: Comments must be received on or before July 1, 2024.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2024–1361 and Airspace Docket No. 24–ANE–05 using any of the following methods:

* *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instructions for sending your comments electronically.

* *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except for Federal holidays.

* *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Docket: Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except for Federal holidays. FAA Order JO 7400.11H Airspace Designations and Reporting Points and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; Telephone: (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *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 **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except for Federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except on federal holidays at the office of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Avenue, College Park, GA 30337.

Incorporation by Reference

Class E airspace designations are published in Paragraph 6002 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11H, Airspace Designations and Reporting Points, dated August 11, 2023, and effective September 15, 2023. These updates will be published in the next update to FAA Order JO 7400.11. FAA Order JO 7400.11 is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA proposes an amendment to 14 CFR part 71 to remove Class E surface airspace for Manchester Boston Regional Airport, Manchester, NH, as the overlying Class C airspace deems the Class E surface airspace unnecessary.

Regulatory Notices and Analyses

The FAA has determined that this proposed 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 will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will 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 final regulatory action by the FAA.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, 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 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 7400.11H, Airspace Designations and Reporting Points, dated August 11, 2023, and effective September 15, 2023, is amended as follows:

Paragraph 6002 Class E Surface Airspace.

* * * * *

ANE NH E2 Manchester, NH [Removed]

Issued in College Park, Georgia, on May 13, 2024.

Patrick Young,

Manager, Airspace & Procedures Team North, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2024–10812 Filed 5–16–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2024–C–2295]

Lonza Greenwood LLC; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Lonza Greenwood LLC, proposing that the color additive regulations be amended to provide for the safe use of sodium copper chlorophyllin in dietary supplement capsules in an amount ranging from 0.08 to 0.4 percent of the weight of the capsule, and to add fescue grass (*Festuca arundinacea*) as a permitted source of the color additive.

DATES: The color additive petition was filed on March 26, 2024.

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

FOR FURTHER INFORMATION CONTACT: Stephen DiFranco, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2710.

SUPPLEMENTARY INFORMATION: Under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(d)(1)), we are giving notice that we have filed a color additive petition (CAP 4C0330), submitted by Intertek Health Sciences, Inc. on behalf of Lonza Greenwood LLC, 2233 Argentia Rd., Suite 201, Mississauga, ON, Canada L5N 2X7. The petition proposes to amend the color additive regulations in 21 CFR 73.125, *Listing of Color Additives Exempt from Certification: Sodium copper chlorophyllin* to provide for the safe use of sodium copper chlorophyllin in dietary supplement capsules in an amount ranging from 0.08 to 0.4 percent of the weight of the capsule, and to add fescue grass (*Festuca arundinacea*) as a permitted source of the color additive.

The petitioner claims that this action is categorically excluded under 21 CFR 25.32(k) because the substance is intended to remain in food through ingestion by consumers and is not intended to replace macronutrients in food. In addition, the petitioner states that, to their knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: May 14, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–10888 Filed 5–16–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–101552–24]

RIN 1545–BR09

Election To Exclude Certain Unincorporated Organizations Owned by Applicable Entities From Application of the Rules on Partners and Partnerships; Hearing Cancellation

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Cancellation of a notice of public hearing on a proposed rulemaking and notice of public hearing.

SUMMARY: This document cancels a public hearing on proposed regulations that would modify existing regulations to allow certain unincorporated organizations that are organized exclusively to produce electricity from certain property to be excluded from the application of partnership tax rules.

DATES: The public hearing scheduled for May 20, 2024, at 10 a.m. ET is cancelled.

FOR FURTHER INFORMATION CONTACT: Vivian Hayes of the Publications and Regulations Section, Associate Chief Counsel (Procedure and Administration) at (202) 317–6901 (not a toll-free number).

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking and a notice of public hearing that appeared in the **Federal Register** on March 11, 2024 (89 FR 17613), announced that a public hearing being held in person and by teleconference was scheduled for May 20, 2024, at 10 a.m. ET. The subject of the public hearing is under 26 CFR part 1.

The public comment period for these regulations expired on May 10, 2024. The notice of proposed rulemaking and notice of public hearing instructed those interested in testifying at the public hearing to submit a request to testify and an outline of the topics to be addressed. We did not receive a request to testify at the Public Hearing. Therefore, the public hearing scheduled for May 20, 2024, at 10 a.m. ET is cancelled.

Oluwafunmilayo A. Taylor,

Section Chief, Publications and Regulations Section, Associate Chief Counsel (Procedure & Administration).

[FR Doc. 2024–10996 Filed 5–15–24; 4:15 pm]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[REG–123376–22]

RIN 1545–BQ74

Disclosures of Return Information Reflected on Returns to Officers and Employees of the Department of Commerce, Including the Bureau of the Census, for Certain Statistical Purposes and Related Activities; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking; correction.

SUMMARY: This document corrects a notice of proposed rulemaking (REG–123376–22) published in the **Federal Register** on March 29, 2024, containing proposed amendments to the regulations relating to the disclosure of specified return information to the Bureau of the Census (Bureau).

DATES: The deadline for submitting written or electronic comments on the proposed rule was April 29, 2024.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, contact Elizabeth Erickson of the Office of the Associate Chief Counsel (Procedure and Administration), at (202) 317–6834 (not a toll-free number); concerning submissions of comments or the public hearing, Vivian Hayes, (202) 317–6901 (not toll-free number) or by email to *publichearings@irs.gov* (preferred).

SUPPLEMENTARY INFORMATION:

Background

The notice of proposed rulemaking (REG–123376–22) that is the subject of this correction is under section 6103 (j)(1)(A) of the Code.

Need for Correction

As published, the notice of proposed rulemaking (REG–123376–22) contains errors that needs to be corrected.

Correction of Publication

Accordingly, the notice of proposed rulemaking (REG–123376–22) that is the subject of FR Doc. 2024–06756, published on March 29, 2024, is corrected on page 22106, in § 301.6103(j)(1)–1, in the first column, the third line of paragraph (b)(3)(iii) is corrected to read, ''pursuant to paragraph (b)(1)(ii)(H)(*1*), (*2*),''.

Oluwafunmilayo A. Taylor,

Section Chief, Publications and Regulations Section, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2024–10871 Filed 5–16–24; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[USCG–2024–0346]

RIN 1625–AA00

Safety Zone; Atlantic Ocean, Virginia Beach Oceanfront, VA; Air Show

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a temporary safety zone for certain waters in the vicinity of the Virginia Beach oceanfront. This action is necessary to provide for the safety of life on these navigable waters during an air show. This proposed rulemaking would prohibit persons and vessels from entry in the safety zone unless authorized by the Captain of the Port Sector Virginia (COTP) or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before June 17, 2024.

ADDRESSES: You may submit comments, identified by docket number USCG–2024–0346, using the Federal Decision-Making Portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email LCDR Ashley Holm, Chief, Waterways Management Division, U.S. Coast Guard; 757–617–7986, *Ashley.E.Holm@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, Purpose, and Legal Basis

On April 4, 2024, the National Air, Sea, and Space Foundation notified the Coast Guard that the 2024 NATO Joint Power Demo Air Show will be occurring Tuesday, August 20, 2024, to Wednesday, August 21, 2024, from 2 p.m. to 2:30 p.m. each day. The air show includes an aerial performance area over a portion of the Virginia Beach oceanfront, where high powered jet aircraft will perform aerobatic maneuvers. The Captain of the Port, Sector Virginia (COTP) has determined that, due to the hazards associated with the air show, a safety zone is needed to ensure the safety of vessels on the navigable water. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70034.

III. Discussion of Proposed Rule

The COTP is proposing to establish a temporary safety zone to protect the public from potential hazards associated with an air show. The safety zone would cover all navigable waters from the shoreline of the Atlantic Ocean at the Virginia Beach Oceanfront contained within the following points: 36°53′10″ N, 075°58′57″ W; 36°53′27″ N, 075°57′22″ W; 36°51′31″ N, 075°56′48″ W; 36°51′14″ N, 075°58′23″ W. The safety zone would be in effect for two days, but it would only be enforced for a half hour each day. The enforcement periods are intended to ensure the safety of vessels on these navigable waters during the air show and to limit the impact of the safety zone on vessel traffic to the time the air show is taking place. No vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed 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 NPRM has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, duration, and time-of-day of the safety zone. Vessel traffic would be able to safely transit around this safety zone which would impact a small, designated area of the Atlantic Ocean at the Virginia Beach oceanfront while the air show is taking place. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

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

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

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 proposed rule. If the proposed 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. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would 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 proposed 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 proposed rule does not have Tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments) because it would not have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. If you believe this proposed rule has implications for federalism or Indian Tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

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 proposed rule would not result in such an expenditure, we do discuss the potential effects of this proposed rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed 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 made a preliminary determination 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 proposed rule involves a safety zone lasting less than 1 hour, each day of the two-day event, that would prohibit entry within a small portion of the Atlantic Ocean at the Virginia Beach Oceanfront. Normally such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A preliminary 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. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

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.

V. Public Participation and Request for Comments

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

Submitting comments. We encourage you to submit comments through the Federal Decision-Making Portal at *https://www.regulations.gov.* To do so, go to *https://www.regulations.gov,* type USCG–2024–0346 in the search box and click ''Search.'' Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using *https://www.regulations.gov,* call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

Viewing material in docket. To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select ''Supporting & Related Material'' in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the *https://www.regulations.gov* Frequently Asked Questions web page. Also, if you click on the Dockets tab and then the proposed rule, you should see a ''Subscribe'' option for email alerts. The option will notify you when comments are posted, or a final rule is published.

We review all comments received, but we will only post comments that address the topic of the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

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, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T05–0346 to read as follows:

§ 165.T05–0346 Safety Zone; Atlantic Ocean, Virginia Beach Oceanfront, VA; Air Show.

(a) *Location.* The following area is a safety zone: all navigable waters from the shoreline of the Atlantic Ocean at the Virginia Beach Oceanfront contained within the following points: 36°53′10″ N, 075°58′57″ W; 36°53′27″ N, 075°57′22″ W; 36°51′31″ N, 075°56′48″ W; 36°51′14″ N, 075°58′23″ W.

(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, Sector Virginia (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by VHF–FM Channel 16. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section will be enforced August 20, 2024, and August 21, 2024, from 2 p.m. to 2:30 p.m. each day.

Dated: May 10, 2024.

J.A. Stockwell,

Captain, U.S. Coast Guard, Captain of the Port, Sector Virginia.

[FR Doc. 2024–10864 Filed 5–16–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF EDUCATION

34 CFR Chapter VI

[Docket ID ED–2024–OPE–0065]

Research and Development Infrastructure Grant

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Proposed priorities, requirements, and definitions.

SUMMARY: The Department of Education (Department) proposes priorities, requirements, and definitions for use in the Research and Development Infrastructure (RDI) grant program. The Department may use one or more of these priorities, requirements, and definitions for competitions in fiscal year (FY) 2024 and later years. We intend for these priorities, requirements, and definitions to help Historically Black Colleges and Universities (HBCUs), Tribally Controlled Colleges and Universities (TCCUs), and Minority-Serving Institutions (MSIs) implement transformational investments in research infrastructure, including research productivity, faculty expertise, graduate programs, physical infrastructure, human capital development, and partnerships leading to increases in external funding.

DATES: We must receive your comments on or before June 17, 2024.

ADDRESSES: Comments must be submitted via the Federal eRulemaking Portal at *www.regulations.gov.* However, if you require an accommodation or cannot otherwise submit your comments via *www.regulations.gov,* please contact the program contact person listed under **FOR FURTHER INFORMATION CONTACT**. The Department will not accept comments submitted by fax or by email, or comments submitted after the comment period closes. To ensure the Department does not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

Federal eRulemaking Portal: Go to *www.regulations.gov* to submit your comments electronically. Information on using *Regulations.gov*, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under ''FAQ.''

Note: The Department's policy is generally to make comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov.* Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: Jason Cottrell, Ph.D., U.S. Department of Education, 400 Maryland Avenue SW, Room 5C122, Washington, DC 20202–4260. Telephone: (202) 453–7530. Email: *Jason.Cottrell@ed.gov.*

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION:

Invitation to Comment: We invite you to submit comments regarding the proposed priorities, requirements, and definitions. To ensure that your comments have maximum effect in developing the final priorities, requirements, and definitions, we urge you to clearly identify the specific section of the proposed priorities, requirements, and definitions that each comment addresses.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866, 13563, and 14094 and their overall requirement of reducing regulatory burden that might result from these proposed priorities, requirements, and definitions. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect public comments about the proposed priorities, requirements, and definitions by accessing *Regulations.gov.* To inspect comments in person, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for these proposed priorities, requirements, and definitions. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Purpose of Program: The RDI grant program is designed to provide HBCUs, TCCUs, and MSIs, including Asian American and Native American Pacific Islander Serving Institutions (AANAPISIs), Alaska Native and Native Hawaiian Serving Institutions (ANNH), Hispanic Serving Institutions (HSIs), Native American Serving Non-Tribal Institutions (NASNTIs), and Predominantly Black Institutions (PBIs), and consortia led by an eligible institution of higher education, with funds to implement transformational investments in research infrastructure, including research productivity, faculty expertise, graduate programs, physical infrastructure, human capital development, and partnerships leading to increases in external and sustained funding.

Program Authority: 20 U.S.C. 1138–1138d.

Background: The Nation's HBCUs, TCCUs, and MSIs provide access to a postsecondary education for many of the Nation's students of color. In the fall of 2022, the 96 Title-IV participating HBCUs (those that offer associate's and/or bachelor's degrees) enrolled 10 percent of all undergraduate Black or African American students and, between July 2021 and June 2022, they conferred 9.3 percent of all associate's and bachelor's degrees to Black or African American students.[1] In 2022–2023, HSIs represented 20 percent of the Nation's institutions and educated 63 percent of the Nation's Hispanic

[1] U.S. Department of Education, National Center for Education Statistics, Integrated Postsecondary Education Data System (IPEDS), Completions and Fall Enrollment components.

undergraduate students.[2] In the Fall of 2021, the 35 Title IV degree-granting TCCUs enrolled over 13,000, or 14 percent, of the Nation's American Indian and Alaska Native undergraduate students.[3] Between July 2021 and June 2022, twenty of those TCCUs cumulatively conferred 380 bachelor's degrees to American Indian and Alaska Native students, representing 87.4 percent of all bachelor's degrees conferred by TCCUs.[4]

Because of their central role in educating students of color, it is important for HBCUs, TCCUs, and MSIs to have the resources they need to excel in research activity. Teaching and research go hand-in-hand in ensuring student[5] and institutional success.[6] Research activity can impact funding, faculty and student recruitment and retention, and student research opportunities, and promote diversity in graduate students and faculty at an institution.

HBCUs, TCCUs, and many MSIs often lack the resources to plan, implement, and promote transformational investments in research infrastructure. According to a report from the Center for American Progress,[7] ''Black researchers, inventors, and entrepreneurs have not had equitable access to capital to seed that innovation and research.'' A report on Federal funding by the National Institutes of Health found that Black researchers are less likely to get access to Federal funds.[8] Another study on the Small Business Innovation Research program found that only 0.3 percent of grants went to teams with a Black principal investigator.[9] HBCUs receive fewer research and development dollars than predominantly white institutions.[10] Yet, according to the National Science Foundation, HBCUs account for seven of the top eight institutions that graduate the highest number of Black undergraduates who go on to earn doctorates in science and engineering.[11] Further, HBCUs enroll only 9 percent of Black undergraduates in the United States, but they account for a much higher percentage of Black students who graduate with degrees in critical fields such as engineering, mathematics, and biological sciences.

TCCUs play a critical role in educating Native students and provide opportunities to produce research on American Indian issues from an American Indian and Alaska Native perspective.[12] According to the National Academies, data provided to their committee looking at MSIs and STEM showed that 93 percent of the students enrolled in STEM programs at four-year TCCUs in the Fall of 2016 were Native American and Alaska Natives.[13] However, TCCUs face obstacles in their efforts to sustain and implement extensive research activities. Administrations often have difficulty maintaining research activities due to the young nature of the institutions and their lack of research support offices.[14] One study found that TCCUs' biggest obstacles in developing research activities are scheduling, infrastructure needs (*i.e.,* lack of space, equipment, and literature), partnership challenges (*i.e.,* lack of Tribal community knowledge), faculty capacity, and mistrust inside and outside of Tribal communities.[15] Additionally, recent events like the COVID–19 pandemic have further demonstrated and exacerbated areas that need improvements to overcome barriers, including technology infrastructure, funding constraints (*i.e.,* long-term funding),[16] and isolation (*i.e.,* remote areas).[17] However, one study found that the potential benefits of research activities for faculty and student development—such as knowledge production and dissemination through conferences, collaborations, and presentations—may far outweigh the costs of overcoming these obstacles. For example, faculty have reported that research opportunities have allowed them to introduce to their classes new information that was not previously available. Additionally, many researchers emphasized that Tribal college research is ''more culturally sensitive and community-grounded, both in the methods and in the results.'' [18]

The Carnegie Classification System is one way of determining whether HBCUs and MSIs are lagging behind in research infrastructure. The American Council on Education (ACE) uses the Carnegie Classification System to categorize institutions based on function and mission. The Doctoral Universities have been categorized into three groups. These groupings are Doctoral Universities with Very High Research Activity (R1), Doctoral Universities with High Research Activity (R2), and Research Colleges and Universities (RCU). According to the most recent ACE Carnegie Classification 2019–20 dashboard,[19] of the 146 Doctoral Universities with Very High Research Activity (R1) universities, there are no HBCUs and only 15 MSIs. Of the 133 Doctoral Universities with High Research Activity (R2) universities, only 11 are HBCUs and 23 are MSIs. ACE will change how these categories are defined in 2025. TCCUs have their own Carnegie Classification and are not included in the R1, R2, or RCU classifications.

The RDI grant program will support institutions in increasing their level of research activity in alignment with the Carnegie Classification designations. The first three proposed priorities would establish separate funding categories for each of the HBCU, TCCU, and MSI institutional types. This approach would enable the Department to meet the congressional intent regarding types of institutions to be served, as outlined in the explanatory statement accompanying Division D of the Further Consolidated Appropriations Act, 2024 (Pub. L. 118–47) and to make awards to institutions under each of these categories.

[2] Excelencia in Education. (2023). *Hispanic-Serving Institutions (HSIs) Fact Sheet: 2022–23.*

[3] U.S. Department of Education, IPEDS, Fall Enrollment component.

[4] U.S. Department of Education, IPEDS, Completions component.

[5] NSSE. (n.d.). Digging Deeper Into the Quality of High-Impact Practices: HIPs Must be ''Done Well'' to Achieve Benefits.

[6] Rosowsky, D. (2022, March 2). The Role of Research at Universities: Why it Matters. In *Forbes.com.*

[7] Center for American Progress. (2020). Redesigning Federal Funding of Research and Development.

[8] Ginther, D.K., Schaffer, W.T., Schnell, J., Masimore, B., Liu, F., Haak, L.L., & Kington R. Race, Ethnicity, and NIH Research Awards. Science. 2011 Aug 19;333(6045):1015–9. doi: 10.1126/science.1196783. PMID: 21852498; PMCID: PMC3412416.

[9] Nager, A., Hart, D., Ezell, S., & Atkinson, R.D. (2016). The Demographics of Innovation in the United States.

[10] Congressional Research Service. (2011). Federal Research and Development Funding at Historically Black Colleges and Universities.

[11] Wondwossen, W. (2020). The Science Behind HBCU Success. National Science Foundation.

[12] Stull, G., Spyridakis, D., Gasman, M., Castro Samayoa, A., Booker, Y. (2015). Redefining Success: How Tribal Colleges and Universities Build Nations, Strengthen Sovereignty, and Persevere Through Challenges.

[13] Espinosa, L.L, McGuire, K., Miles Jackson, L. (2019). Minority Serving Institutions: Americans Underutilized Resource for Strengthening the STEM Workforce.

[14] Riley, E.T., Vadiee, N., & Ganguli, A. (2017). The Evolution of Research at Tribal Colleges and Universities. In Tribal College Journal, 29(2).

[15] Mortensen, M. (2001). Survey of Tribal Colleges Reveals Research's Benefits, Obstacles. In Tribal College Journal, 13(2).

[16] Redden, E. (2021, March 15). Trying Times for Tribal Colleges. In Inside Higher Ed.

[17] Stull, G., Spyridakis, D., Gasman, M., Castro Samayoa, A., & Booker, Y. (2015). Redefining Success: How Tribal Colleges and Universities Build Nations, Strengthen Sovereignty, and Persevere Through Challenges.

[18] Mortensen, M. (2001). Survey of Tribal Colleges Reveals Research's Benefits, Obstacles. In Tribal College Journal, 13(2).

[19] *https://carnegieclassifications.acenet.edu/.*

The fourth proposed priority would establish a priority for institutions with an enrollment of Pell Grant recipients that accounts for 50 percent or higher of their undergraduate student enrollment. The explanatory statement language for this program articulated the intent for these grants to provide ''transformational'' investments to improve institutions' research and development infrastructure. The Department believes these funds have the highest potential to transform an institution's Research and Development infrastructure if they are targeted to the institutions that enroll the highest percentage of students from low-income backgrounds. The Pell metric remains the best indicator of that.

Proposed Priorities

We propose four priorities. We may use one or more of these priorities in any year in which this program is in effect.

Proposed Priority 1: Funding for Historically Black Colleges and Universities' Research and Development Infrastructure.

Projects proposed by HBCUs to implement high-quality transformative research capacity initiatives and designed to move the institution from R2 to R1, or from RCU to R2, research activity status.

Proposed Priority 2: Funding for Tribally Controlled Colleges and Universities' Research and Development Infrastructure.

Projects proposed by TCCUs to improve their research and development activities, including infrastructure, faculty development, and academic programs.

Proposed Priority 3: Funding for Minority-Serving Institutions' Research and Development Infrastructure.

Projects proposed by MSIs to implement high-quality transformative research capacity initiatives and designed to move the institution from R2 to R1, or from RCU to R2, research activity status.

Proposed Priority 4: MSI Pell Grant Percentage.

Projects proposed by lead applicants with an enrollment of Pell Grant recipients that accounts for 50 percent or higher of their undergraduate student enrollment, as measured by the Department using the most recent data available in the Integrated Postsecondary Education Data System (IPEDS).

Types of Priorities

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register**. The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

Proposed Requirements: The Department proposes the following program requirements for this program. We may apply one or more of these requirements in any year in which this program is in effect and may limit the application of these requirements to one or more of the proposed priorities. The Department will announce within the notice inviting applications the final requirements that will apply to a particular grant competition, and whether those requirements will apply to grantees applying under each proposed priority for this program.

Proposed Requirement–1—Use of Funds.

Background: RDI is funded under the Fund for the Improvement of Postsecondary Education (FIPSE) authority and was first authorized in FY 2023 as described in the explanatory statement accompanying Division H of the Consolidated Appropriation Act, 2023 (Pub. L. 117–328). As noted elsewhere in this document, Congress directed the Department through the explanatory statement accompanying Division D of the Further Consolidated Appropriations Act, 2024 (Pub. L. 118–47) to provide continued funding for this program. In order to fully implement this program in the manner that Congress has directed, the Department proposes the following Uses of Funds to provide specificity about the allowable activities to applicants and grantees under this program. The Department believes each of these activities would support the overall goal of the RDI program.

Requirement: Grantees must conduct one or more of the following activities:

(1) Providing for the improvement of infrastructure existing on the date of the grant award, including deferred maintenance, or the establishment of new physical infrastructure, including instructional program spaces, laboratories, and research facilities relating to the fields of science, technology, engineering, the arts, mathematics, health, agriculture, education, medicine, law, and other disciplines.

(2) Hiring and retaining faculty, students, research-related staff, or other personnel, including research personnel skilled in operating, using, or applying technology, equipment, or devices to conduct or support research.

(3) Supporting research internships and fellowships for students, including undergraduate, graduate, and post-doctoral positions, which may include providing direct student financial assistance and other supports to such students.

(4) Creating new, or expanding existing, academic positions, including internships, fellowships, and post-doctoral positions, in fields of research for which research and development infrastructure funds have been awarded to the grantee under this program.

(5) Creating and supporting inter- and intra-institutional research centers (including formal and informal communities of practice) in fields of research for which research and development infrastructure funds have been awarded to the grantee under this program, including hiring staff, purchasing supplies and equipment, and funding travel to relevant conferences and seminars to support the work of such centers.

(6) Building new institutional support structures and departments that help faculty learn about, and increase faculty and student access to, Federal research and development grant funds and non-Federal academic research grants.

(7) Building data and collaboration infrastructure so that early findings and research can be securely shared to facilitate peer review and other appropriate collaboration.

(8) Providing programs of study and courses in fields of research for which research and development infrastructure funds have been awarded to the grantee under this program.

(9) Paying operating and administrative expenses for, and coordinating project partnerships with members of, the consortium on behalf of which the eligible institution has received a grant under this program, provided that grantees may not pay for the expenses of any R1 institutions that are members of the consortia.

(10) Installing or extending the life and usability of basic systems and components of campus facilities related to research, including high-speed broadband internet infrastructure sufficient to support digital and technology-based learning.

(11) Expanding, remodeling, renovating, or altering biomedical and behavioral research facilities existing on the date of the grant award that received support under section 404I of the Public Health Service Act (42 U.S.C. 283k).

(12) Acquiring and installing furniture, fixtures, and instructional research-related equipment and technology for academic instruction in campus facilities in fields of research for which research and development infrastructure funds have been awarded to the grantee under this program.

(13) Providing increased funding to programs that support research and development at the eligible institution that are funded by the National Institutes of Health, including through their Path to Excellence and Innovation program.

(14) Faculty professional development.

(15) Planning purposes.

Proposed Requirement 2—Indirect Cost Rate Information.

Background: In order to maximize the grant resources that support direct costs, the Department is proposing to limit indirect costs to 8 percent of a modified total direct cost base.

Requirement: A grantee's indirect cost reimbursement is limited to 8 percent of a modified total direct cost base. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *www.ed.gov/about/offices/list/ocfo/intro.html.*

Proposed Requirement 3—Matching Requirements and Exceptions.

Background: The Department proposes to require that grantees provide a 1:1 match of non-Federal to Federal contributions. This proposed requirement is intended to leverage the Federal funds to double the impact of overall project plans, to promote the sustainability of the activities funded under this program, and to ensure alignment of such activities to the institution's strategic plan. The Department also proposes waiver authority so that institutions located in areas with high rates of poverty, that enroll high numbers of students from low-income backgrounds, or that are otherwise under resourced such that complying with this matching requirement would be overly burdensome, can still benefit from this program.

Requirement: Grantees must provide a 1:1 match, which can include in-kind donations.

Waiver Authority: The Secretary may waive the matching requirement on a case-by-case basis upon showing any of the following exceptional circumstances: (i) The difficulty of raising matching funds for a program to serve an area with high rates of poverty in the lead applicant's geographic location, defined as a Census tract, a set of contiguous Census tracts, an American Indian Reservation, Oklahoma Tribal Statistical Area (as defined by the U.S. Census Bureau), Alaska Native Village Statistical Area or Alaska Native Regional Corporation Area, Native Hawaiian Homeland Area, or other Tribal land or county that has a poverty rate of at least 25 percent as determined every 5 years using American Community Survey 5-Year data; (ii) Serving a significant population of students from low-income backgrounds at the lead applicant location, defined as at least 50 percent (or the eligibility threshold for the appropriate institutional sector available at *https://www2.ed.gov/about/offices/list/ope/idues/eligibility.html#app*) of degree-seeking enrolled students receiving need-based grant aid under Title IV of the HEA; (iii) Significant economic hardship as demonstrated by low average educational and general expenditures per full-time equivalent undergraduate student at the lead applicant institution, in comparison with the average educational and general expenditures per full-time equivalent undergraduate student of institutions that offer similar instruction without need of a waiver, as determined by the Secretary in accordance with the annual process for designation of eligible Titles III and V institutions.; or (iv) Information that otherwise demonstrates a commitment to the long-term sustainability of the applicant's projects, such as evidence of a consortium relationship with an R1 institution, a State bond, State matching, planning documents such as a campus plan, multi-year faculty hiring plan, support of industry, Federal grants received, or a demonstration of institutional commitment that may include commitment from the institution's board.

Proposed Requirement 4: Limitation on Grant Awards.

Background: The Department proposes to allow the Secretary, in a given RDI competition, to limit eligibility for new awards to applicants without current active grants under this program. This proposed requirement is designed to increase the number of eligible institutions that can benefit from this program. The Department also believes that it would be inappropriate to allow institutions to have multiple grants concurrently under this program because the objective of this program is inherently an institution-wide objective. Furthermore, since many of the activities that institutions can undertake under this program are inherently institution-wide activities, this proposed requirement would remove the risk that these funds could support duplicative activities.

Requirement: The Department will only make awards to applicants that are not the individual or lead applicant in a current active grant from the RDI grant program.

Proposed Definitions: The Department proposes the following definitions for this program. We may apply these definitions in any year in which this program is in effect. The proposed definitions for R1, R2, and RCU would align with the ACE Carnegie Classifications that will be in effect starting in 2025. The proposed definition of ''underrepresented students'' is intended for use in the performance measures the Department uses to evaluate the success of the RDI grant program, for example, a performance measure based on the number of doctorates conferred to underrepresented students annually.

Research 1: Very High Research Spending and Doctorate Production (R1) means that an institution has spent at least $50 million in total research and development (R&D) in a year, as reported to the National Science Foundation (NSF) Higher Education Research and Development (HERD) Survey, and awarded at least 70 research/scholarship doctorates in a year, as reported to IPEDS.

Research 2: High Research Spending and Doctorate Production (R2) means that an institution has spent at least $5 million in total R&D in a year, as reported to the NSF HERD Survey, and awarded at least 20 research/scholarship doctorates in a year, as reported to IPEDS. It does not include institutions designated R1.

Research Colleges and Universities (RCU) means that an institution has spent at least $2.5 million in total R&D in a year, as reported to the NSF HERD Survey. It does not include institutions designated R1 or R2.

Historically Black College or University means an institution that meets the eligibility requirements under section 322(2) of the Higher Education Act of 1965, as amended (HEA).

Minority-Serving Institution means an institution that is eligible to receive

assistance under sections 317 through 320 of part A of title III, or under title V of the HEA.

Tribal College or University has the meaning ascribed it in section 316(b)(3) of the HEA.

Underrepresented students means students enrolled in postsecondary, career, or technical education who are in one or more of the following subgroups: (i) A student from a low-income background. (ii) A student who is American Indian, Alaska Native, Asian American, Black, Hispanic or Latino, Native Hawaiian, and/or Pacific Islander.

Final Priorities, Requirements, and Definitions

We will announce the final priorities, requirements, and definitions in a document in the **Federal Register**. We will determine the final priorities, requirements, and definitions after considering public comments on the proposed priorities, requirements, and definitions and other information available to the Department. This document does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This document does *not* solicit applications. In any year in which we choose to use one or more of these priorities, requirements, and definitions, we invite applications through a notice in the **Federal Register**.

Executive Orders 12866, 13563, and 14094

Regulatory Impact Analysis

Under Executive Order 12866, the Office of Management and Budget (OMB) determines whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive order and subject to review by OMB. Section 3(f) of Executive Order 12866, as amended by Executive Order 14094, defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $200 million or more (adjusted every three years by the Administrator of Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or Tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise legal or policy issues for which centralized review would meaningfully further the President's priorities, or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

This proposed regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866, as amended by Executive Order 14094.

We have also reviewed this proposed regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866, as amended by Executive Order 14094. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

We are issuing these proposed priorities, requirements, and definitions only on a reasoned determination that their benefits would justify their costs. In choosing among alternative regulatory approaches, we selected those approaches that would maximize net benefits. Based on the analysis that follows, the Department believes that this regulatory action is consistent with the principles in Executive Order 13563.

The potential costs associated with these priorities, requirements, and definitions would be minimal, while the potential benefits are significant. The Department believes that this proposed regulatory action would not impose significant costs on eligible entities. Participation in this program is voluntary, and the costs imposed on applicants by this regulatory action would be limited to paperwork burden related to preparing an application. The potential benefits of implementing the program would outweigh the costs incurred by applicants, and the costs of carrying out activities associated with the application would be paid for with program funds. For these reasons, we have determined that the costs of implementation would not be burdensome for eligible applicants, including small entities.

We also have determined that this regulatory action would not unduly interfere with State, local, and Tribal governments in the exercise of their governmental functions.

In accordance with these Executive orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

Clarity of the Regulations

Executive Order 12866 and the Presidential memorandum ''Plain Language in Government Writing'' require each agency to write regulations that are easy to understand. The Secretary invites comments on how to make these proposed priorities, requirements, and definitions easier to understand, including answers to questions such as the following:

- Are the requirements in the proposed priorities, requirements, and definitions clearly stated?
- Do the proposed priorities, requirements, and definitions contain technical terms or other wording that interferes with their clarity?

• Does the format of the proposed priorities, requirements, and definitions (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce their clarity?
• Would the proposed priorities, requirements, and definitions be easier to understand if we divided them into more (but shorter) sections?
• Could the description of the proposed priorities, requirements, and definitions in the **SUPPLEMENTARY INFORMATION** section of this preamble be more helpful in making the proposed priorities, requirements, and definitions easier to understand? If so, how?
• What else could we do to make the proposed priorities, requirements, and definitions easier to understand?

To send any comments that concern how the Department could make these proposed priorities, requirements, and definitions easier to understand, see the instructions in the **ADDRESSES** section.

Intergovernmental Review: This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Regulatory Flexibility Act Certification

The Secretary certifies that these proposed priorities, requirements, and definitions would not have a significant economic impact on a substantial number of small entities.

The small entities that this proposed regulatory action would affect are institutions that meet the eligibility requirements described in 316 through 320 of part A of title III, part B of title III, or title V of the HEA. The Secretary believes that the costs imposed on applicants by the proposed priorities, requirements, and definitions would be limited to paperwork burden related to preparing an application and that the benefits would outweigh any costs incurred by applicants.

Participation in this program is voluntary. For this reason, the proposed priorities, requirements, and definitions would impose no burden on small entities unless they applied for funding under the program. We expect that in determining whether to apply for RDI grant program funds, an eligible applicant would evaluate the requirements of preparing an application and any associated costs and weigh them against the benefits likely to be achieved by receiving an RDI program grant. Eligible applicants most likely would apply only if they determine that the likely benefits exceed the costs of preparing an application. The likely benefits include the potential receipt of a grant as well as other benefits that may accrue to an entity through its development of an application, such as the use of that application to seek funding from other sources to address the institution's research and development infrastructure needs.

This proposed regulatory action would not have a significant economic impact on a small entity once it receives a grant because it would be able to meet the costs of compliance using the funds provided under this program. We invite comments from eligible small entities as to whether they believe this proposed regulatory action would have a significant economic impact on them and, if so, request evidence to support that belief.

Paperwork Reduction Act of 1995

These proposed priorities, requirements, and definitions do not contain any information collection requirements.

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov*. At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov*. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Nasser Paydar,

Assistant Secretary for Postsecondary Education.

[FR Doc. 2024–10870 Filed 5–16–24; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2023–0518; FRL–11955–01–R4]

Air Plan Approval; GA; Revisions to the State Implementation Plan Gasoline Transport Vehicles and Vapor Collection System Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a State Implementation Plan (SIP) revision submitted by the Georgia Department of Natural Resources (GA DNR) Environmental Protection Division (EPD) on September 28, 2023, for the purpose of clarifying requirements for gasoline transport vehicles and making minor administrative changes. EPA is proposing to approve Georgia's September 28, 2023, SIP revision pursuant to the Clean Air Act (CAA or Act).

DATES: Comments must be received on or before June 17, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2023–0518 at *regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general

guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Weston Freund, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–8773. Mr. Freund can also be reached via electronic mail at staff email *freund.weston@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. EPA's Analysis of Georgia's Submittal

EPA is proposing to approve a SIP revision submitted by the Georgia EPD on September 28, 2023, amending Rule 391–3–1–.02(2)(ss), ''Gasoline Transport Vehicles and Vapor Collection Systems'' [1] to clarify requirements for tank labeling and increase consistency with other rules. The SIP revision makes the following changes: replaces ''paragraph'' with ''subparagraph'' in Rule 391–3–1–.02(2)(ss)1.; adds ''(month and year)'' to Rule 391–3–1–.02(2)(ss)1.(ii) to clarify that ''date'' means month and year; changes the first letter of ''subparagraph'' to lower case in Rule 391–3–1–.02(2)(ss)2.(ii), and replaces ''section'' with ''paragraph'' in Rule 391–3–1–.02(2)(ss)3. to be consistent with the rest of the rule. EPA is proposing to approve these changes because they are administrative in nature and would therefore not interfere with any applicable requirement concerning attainment and reasonable further progress or any other applicable requirement of the CAA.[2]

II. Incorporation by Reference

In this document, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, and as discussed in Section I of this preamble, EPA is proposing to incorporate by reference Georgia Rule 391–3–1–.02(2)(ss), ''Gasoline Transport Vehicles and Vapor Collection Systems'', which changes ''paragraph'' to ''subparagraph'' in Rule 391–3–1–.02(2)(ss)1., adds ''(month and year)'' to Rule 391–3–1–.02(2)(ss)1.(ii), changes ''subparagraph'' to lower case in Rule 391–3–1–.02(2)(ss)2.(ii), and changes ''section'' to ''paragraph'' in Rule 391–3–1–.02(2)(ss)3., state effective on September 17, 2023. EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 4 office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

III. Proposed Action

EPA is proposing to approve the aforementioned Georgia SIP revision consisting of administrative changes to Rule 391–3–1–.02(2)(ss), ''Gasoline Transport Vehicles and Vapor Collection Systems'' for the reasons discussed above.

IV. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 14094 (88 FR 21879, April 11, 2023);
- 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 subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- 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.

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).

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. 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.'' 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.''

GA EPD did not evaluate EJ considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. EPA did not perform an EJ analysis and did not consider EJ in this proposed action. Due to the nature of the action being proposed here, this proposed action is expected to have a neutral to positive impact on the air quality of the affected area. Consideration of EJ is not required as part of this proposed action, and there is no information in the record inconsistent with the stated goal of E.O. 12898 of achieving EJ for people of color, low-income populations, and Indigenous peoples.

[1] Table 1 to Paragraph (c)—EPA-Approved Georgia Regulations at 40 CFR 52.570(c) incorrectly refers to Rule 391–3–1–.02(2)(ss) as ''Gasoline Transport Systems and Vapor Collection Systems'' rather than ''Gasoline Transport Vehicles and Vapor Collection Systems'' as approved October 13, 1992. *See* 57 FR 46780. In addition to the revisions described herein, EPA is proposing to correct the title of Rule 391–3–1–.02(2)(ss) in 40 CFR 52.570(c) to accurately reflect the title as approved on October 13, 1992.

[2] *See* CAA section 110(l).

List of Subjects in 40 CFR Part 52

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

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

Dated: May 10, 2024.

Jeaneanne Gettle,

Acting Regional Administrator, Region 4.

[FR Doc. 2024–10713 Filed 5–16–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2019–0562; FRL–11960–01–R3]

Air Plan Approval and Disapproval; Pennsylvania; Reasonably Available Control Technology (RACT) for Volatile Organic Compounds (VOC) Under the 2008 Ozone National Ambient Air Quality Standards (NAAQS)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to revise its December 14, 2020 action that fully approved two state implementation plan (SIP) revisions, both submitted to EPA on August 13, 2018 by the Commonwealth of Pennsylvania, through the Pennsylvania Department of Environmental Protection (PADEP). Those SIP revisions addressed reasonably available control technology (RACT) requirements for the 2008 ozone national ambient air quality standards (NAAQS), including those related to control technique guidelines (CTGs) for volatile organic compounds (VOC) and the addition of regulations controlling VOC emissions from industrial cleaning solvents. The SIP revisions also included certain clarifying amendments to Pennsylvania code related to major source RACT regulations. Upon reconsideration, EPA is proposing to revise its prior action to partially approve and partially disapprove the August 13, 2018 submittals. Specifically, EPA is proposing approval of certain clarifying amendments as well as a negative declaration submitted by PADEP. EPA is proposing disapproval of the remainder of both SIP submittals related to CTGs and control of VOC emissions from industrial cleaning solvents. This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before June 17, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R03–OAR–2019–0562 at *www.regulations.gov,* or via email to *goold.megan@epa.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFOMRATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Ellen Schmitt, Planning & Implementation Branch (3AD30), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1600 John F Kennedy Boulevard, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814–5787. Ms. Schmitt can also be reached via electronic mail at *schmitt.ellen@epa.gov.*

SUPPLEMENTARY INFORMATION: On August 13, 2018, PADEP submitted to EPA two SIP revisions to satisfy certain RACT requirements for sources of VOC emissions required by sections 182(b)(2) and 184(b)(l)(B) of the CAA and the implementing regulations for the 2008 8-hour ozone NAAQS (80 FR 12264, March 6, 2015; 40 CFR part 51, subpart AA). Additionally, these two submittals are related to another PADEP SIP submission addressing RACT for major stationary sources of VOC and oxides of nitrogen (NO_X) that was conditionally approved by EPA on May 9, 2019. See section II.B.2 of this proposed rulemaking.

I. Background

A. Ozone NAAQS and RACT Requirements

On July 18, 1997 (62 FR 38856), EPA promulgated a revised standard for ground level ozone based on 8-hour average concentrations. The 8-hour averaging period replaced the previous 1-hour averaging period adopted in 1979, and the level of the NAAQS was changed from 0.12 parts per million (ppm) to 0.08 ppm. On March 27, 2008 (73 FR 16436), EPA further strengthened the 8-hour ozone standards from 0.08 ppm to 0.075 ppm (2008 8-hour ozone NAAQS). On October 26, 2015, (80 FR 65292) EPA adopted another revision to the ozone standard (2015 ozone NAAQS), but the 2008 ozone standard remains in place. This action concerns RACT requirements under the 2008 8-hour NAAQS.

The CAA regulates emissions of NO_X and VOC to prevent photochemical reactions that result in ozone formation. Section 182(b)(2) of the CAA requires states with ozone nonattainment areas classified as moderate or higher to submit a SIP revision requiring implementation of RACT. EPA has consistently defined ''RACT'' as the lowest emission limit that a particular source is capable of meeting by the application of the control technology that is reasonably available considering technological and economic feasibility.

The CAA requires RACT revisions for three specific categories of sources for the ozone NAAQS. First, section 182(b)(2)(A) requires RACT for each category of VOC sources in the nonattainment area covered by a CTG document issued by EPA between November 15, 1990 and the date of attainment.[1] Second, section 182(b)(2)(B) requires RACT for all VOC sources in the area covered by any CTG issued before November 15, 1990. Third, section 182(b)(2)(C) requires RACT for all other major stationary sources of VOC located in the nonattainment area. In addition, section 182(f) subjects major stationary sources of NO_X to the same RACT requirements applicable to major stationary sources of VOC.[2] EPA has not issued any CTGs for categories of NO_X sources, so the effect of section 182(f) is to require that SIPs also require

[1] EPA provides states with guidance concerning what types of controls could constitute RACT for a given source category through the issuance of CTG and alternative control technique (ACT) documents.

[2] A ''major source'' is defined based on the source's potential to emit NO_X or VOC, and the applicable ton per year emission thresholds defining a ''major'' source differ based on the classification of the nonattainment area in which the source is located. See sections 182(c)–(f) and 302 of the CAA.

RACT for major stationary sources of NO_X in accordance with section 182(b)(2)(C). The ozone RACT requirements under section 182(b)(2) are usually referred to as VOC CTG RACT, non-CTG VOC RACT, and major NO_X RACT. In addition, section 184(a) of the CAA established an Ozone Transport Region (OTR) comprised of 12 eastern states, including all of Pennsylvania. Pursuant to section 184(b), the RACT requirements of section 182(b)(2) which would be applicable if an area were classified as a moderate nonattainment area apply to all areas within the OTR. This requirement is referred to as OTR RACT. OTR RACT applies throughout the Commonwealth of Pennsylvania.

On March 6, 2015 (80 FR 12264), EPA published a final rule that outlined the obligations related to required SIP requirements for the 2008 8-hour ozone NAAQS. This rule, herein referred to as the ''2008 ozone implementation rule,'' contained, among other things, a description of EPA's expectations for states with RACT obligations. The 2008 ozone implementation rule indicated that states could meet RACT (1) through the establishment of new or more stringent requirements that meet RACT control levels, (2) a certification that previously adopted RACT controls in their SIP, under a prior ozone NAAQS, represent adequate RACT control levels for the 2008 8-hour ozone NAAQS, or (3) with a combination of these two approaches. In addition, a state could submit a negative declaration in instances where, for a particular CTG, there are no sources within the state covered by that CTG.

In EPA's 2008 ozone implementation rule, the Agency states that ''states should refer to the existing CTGs and ACTs for purposes of meeting their RACT requirements, as well as all relevant information (including recent technical information and information received during the public comment period) that is available at the time that they are developing their RACT SIPs.'' See 80 FR at 12279, March 6, 2015.

B. Challenge to Approval, Court Proceedings, Voluntary Remand, and Reconsideration

On December 14, 2020 (85 FR 80616), EPA published a full approval of PADEP's two August 13, 2018 SIP submittals. The approval was challenged in the U.S. Court of Appeals for the Third Circuit, and on September 3, 2021, that court granted EPA's request for remand without vacatur of the Agency's final full approval.[3]

A petitioner filed litigation in the Eastern District of Pennsylvania on May 16, 2023, arguing EPA had unreasonably delayed in its reconsideration of the final approval of the August 13, 2018 SIP submittals. On December 15, 2023, the court filed a consent decree requiring that EPA complete its reconsideration of the December 14, 2020 final rule by November 15, 2024.[4]

EPA has reconsidered that final full approval and EPA is proposing that it was incorrect to fully approve the August 13, 2018 submittals. Now, EPA is proposing to revise its action to a partial approval and partial disapproval that will disapprove parts of the August 13, 2018 submittals, while leaving intact our prior approval of other sections. The particulars are explained in sections II.A and II.B of this document. See, CAA section 110(k)(6). Specifically, EPA is proposing to approve certain clarifying amendments to major source RACT regulations contained in the submittals, as well as a negative declaration for CTG RACT purposes. EPA is proposing to disapprove the remainder of both August 13, 2018 SIP submittals, including those related to CTGs and control of VOC emissions from industrial cleaning solvents.[5]

If EPA finalizes the disapproval proposed here, that action would commence a sanctions clock under CAA section 179, providing for emission offset sanctions for new or modified sources within the Commonwealth if EPA has not fully approved a revised plan within 18 months after final disapproval, and providing for highway funding sanctions in affected nonattainment areas[6] if EPA has not fully approved a revised plan within six months after the imposition of offset sanctions. The sanctions clock can be stopped only if the conditions of EPA's regulations at 40 CFR 52.31 are met. Pursuant to CAA section 110(c)(1)(B), a final disapproval would also initiate an obligation for EPA to promulgate a Federal implementation plan (FIP) within 24 months unless PADEP has submitted, and EPA has approved, a plan addressing the applicable RACT requirements.

II. Summary of SIP Revision and EPA Analysis

A. Pennsylvania's RACT Certification of CTGs Under the 2008 8-Hour Ozone NAAQS and Request To Incorporate Standards of Performance for New Stationary Sources Into the SIP

The first August 13, 2018 SIP submittal is entitled ''Certification of Reasonably Available Control Technology for Control Techniques Guidelines Under the 2008 Ozone National Ambient Air Quality Standards and Incorporation of 25 Pa Code Chapter 122 (Relating to National Standards of Performance for New Stationary Sources) into the Commonwealth's State Implementation Plan.'' PADEP submitted this SIP revision for the purposes of meeting the RACT requirements under CAA sections 182(b)(2) and 184(b)(1)(B) and implementing the regulations for the 2008 8-hour ozone NAAQS. Specifically, this submittal: (1) certifies that PADEP's adoption and implementation of regulations to control VOC emissions is consistent with EPA's CTGs and represents RACT for these covered CTG sources for the 2008 ozone standard; (2) incorporates 25 Pa. Code Chapter 122 (relating to national standards of performance for new stationary sources) into the Pennsylvania SIP and certifies that those provisions continue to represent RACT for facilities subject to such standards of performance; and (3) incorporates specific permit conditions from certain facilities for the purpose of establishing source-specific RACT-level controls for those facilities.

1. CTG Certifications

As noted in section I.A. of this preamble, if an area had been designated as a nonattainment area for the 1979 and 1997 ozone standards, and adopted RACT level controls, the state could review those controls to determine if they still represent RACT for the 2008 8-hour ozone NAAQS. PADEP determined that various regulations consistent with each CTG continues to represent RACT for the 2008 8-hour ozone NAAQS. PADEP

[3] A copy of the court order is located in the docket for this action. Docket Id. EPA–R03–OAR–2019–0562 in *regulations.gov*.

[4] A copy of the court order is located in the docket for this action. Docket Id. EPA–R03–OAR–2019–0562 in *regulations.gov.*

[5] Including: a certification by PADEP that its existing state regulations for sources covered by certain CTGs is RACT for the 2008 8-hour ozone NAAQS; a request that Pennsylvania's incorporation by reference of all Federal NSPS at 25 Pa. Code Chapter 122 be approved into the SIP; and requested the approval into the SIP of source-specific permit conditions for sources subject to the ''CTG for Shipbuilding and Ship Repair Operations Surface Coating'' (61 FR 44050, August 27, 1996) and ''Control of Volatile Organic Compounds Emissions from Air Oxidation Processes in the Synthetic Organic Chemical Manufacturing Industry,'' EPA–450/3–84–015, December 1984.

[6] For the OTR states, such highway sanctions would only apply in nonattainment areas. If the OTR state does not contain any nonattainment areas, then the highway sanctions would not apply in that state.

based this certification on the following: (1) certification that Pennsylvania's regulations meet the CAA RACT requirements, are based on the most currently available technically and economically feasible controls, and represent RACT for implementation purposes pertaining to the 2008 8-hour ozone NAAQS; (2) certification that PADEP has adopted and implemented SIP-approved provisions or regulations addressing applicable EPA CTG source categories and that these provisions or regulations represent RACT control levels or control levels more stringent than RACT under the 2008 8-hour ozone NAAQS; (3) certification that PADEP has implemented all CTG RACT controls indicated in this SIP revision, based on the EPA's guidance and standards, and that they represent current RACT control levels under the 2008 8-hour ozone NAAQS; and (4) certification that PADEP has determined that there is one CTG source category for which it has made a negative declaration because there are no existing sources in Pennsylvania in this source category subject to CTG RACT.

As noted previously, EPA finalized approval of PADEP's two August 13, 2018 SIP submittals on December 14, 2020 and this final approval was voluntarily remanded to EPA for reconsideration on September 3, 2021. The final action was remanded without vacatur so that the Agency could reconsider its approval of PADEP's August 13, 2018 SIP revisions to ensure that Pennsylvania's RACT requirements for sources covered by CTGs satisfy the requirements associated with the 2008 8-hour ozone NAAQS.

Upon reconsideration, and as described more fully in this proposed rulemaking, EPA is proposing to determine that we erred in previously approving the CTG portion of PADEP's RACT certification SIP, as PADEP's certification failed to show sufficient support in the record that the provisions identified as RACT in PADEP's certification fulfills the RACT requirements of the 2008 8-hour ozone NAAQS for CTG sources. As clarified in the 2008 implementation rules, RACT analysis should consider any technical advances since previous approvals of the RACT rules and provide evidence that other relevant information, including recent technical information and information available at the time of adoption, were considered to determine the lowest emission limit that a particular source is capable of meeting by the application of the control technology that is reasonably available considering technological and economic feasibility. PADEP did not provide this analysis. EPA therefore concludes that the PADEP's SIP submittals did not fully evaluate VOC RACT CTG requirements, and the Agency is proposing disapproval of the certification portion of the first August 13, 2018 SIP submittal, with the exception of PADEP's negative declaration for one CTG source category. PADEP determined that there are no sources in Pennsylvania (excluding Philadelphia County and Allegheny County) covered by EPA's CTG ''Control of Volatile Organic Compound Emissions from Large Petroleum Dry Cleaners,'' (EPA–450/3–82–009; September 1982). The record in our original action in support of this negative declaration, as discussed in that action (85 FR at 80617, December 14, 2020, and the associated technical support document (TSD)), was sufficiently robust and well-developed. EPA is proposing to approve PADEP's submitted negative declaration for this CTG source type.

2. Incorporation by Reference of New Source Performance Standards (NSPS)

Pennsylvania has incorporated by reference all of the NSPS promulgated by EPA under section 111 of the CAA and found at 40 CFR part 60. See 25 Pa. Code 122. PADEP determined that for certain source categories, the Federal requirements of 40 CFR part 60—Standards of Performance for New Stationary Sources, provide RACT level control.

Upon reconsideration, EPA is proposing that PADEP's determination that NSPS requirements equal RACT was not supported by a sufficiently robust and well-developed record indicating that, in addition to considering the NSPS themselves, that non-NSPS requirements, including recent technical information and the RACT requirements of other states, had also been reviewed and considered as potential RACT. As stated previously in this preamble, EPA's 2008 ozone implementation rule clarifies that a more demonstrative and robust comparison is needed. EPA is proposing that we erred in our previous approval that certain NSPS provisions meet CTG requirements and therefore are sufficient to implement RACT for those sources for the 2008 8-hour ozone NAAQS. The Agency now proposes disapproval of the portions of PADEP's SIP submittals focused on NSPS providing RACT level control.

3. Incorporation of Source Specific Permit Limits

PADEP found only two sources covered by the ''Shipbuilding/Repair ACT (EPA 453/R–94–032, April 1994) and EPA's CTG for Shipbuilding and Ship Repair Operations (Surface Coating) (61 FR 44050, August 27, 1996)'' and one source subject to ''Control of Volatile Organic Compound Emissions from Air Oxidation Processes in Synthetic Organic Chemical Manufacturing Industry, EPA–450/3–84–015, December 1984.'' Rather than promulgate a rule to address the RACT requirements of those two CTGs for only three affected sources, PADEP incorporated the requirements of the CTGs into Federally enforceable permits and submitted the applicable permit limits for incorporation into the SIP.

Redacted versions of Permit Nos. 25–00930 (Donjon Shipbuilding) and 26–00545 (Heartland Fabrication) were submitted for incorporation into the Commonwealth's SIP. Generally, the control strategy is to limit the VOC content of the coatings and materials used. In its first August 13, 2018 SIP submittal, PADEP stated that the relevant portions of the permits are consistent with the Shipbuilding and Ship Repair Operations (Surface coating) CTG and therefore satisfy the RACT requirements for these sources. A redacted version of Permit No. 39–00024 (Geo. Specialty Chem. Trimet Div.) was also submitted for incorporation into the Pennsylvania SIP. PADEP certified that this is the only source to which the Synthetic Organic Chemical Manufacturing Industry (SOCMI) Air Oxidation Process CTG applies. Pursuant to the CTG, ''It is recommended that air oxidation facilities for which an existing combustion device is employed to control process VOC emissions should not be required to meet the 98 percent emissions limit until the combustion device is replaced for other reasons. In other words, no facility would be required to upgrade or replace an existing control device.'' [7] PADEP determined that the facility's formaldehyde process and catalytic incinerator were installed in 1980, before the December 1984 applicability date of the CTG. PADEP further determined that neither the process nor the control device have been modified since the 1980 installation date. PADEP therefore certified that the existing control strategy and emission

[7] See ''Control of Volatile Organic Compound Emissions from Air Oxidation Processes in the Synthetic Organic Chemical Manufacturing Industry, EPA, 450/3–84–015, December 1984,'' Page 4–1, available at: *www3.epa.gov/airquality/ctgact/198412vocepa4503-84-015airoxidationprocesses.pdf.*

limitations in the permit constitute RACT for this particular source.

Similar to EPA's justification for disapproving the previous submittal elements, upon reconsideration, EPA is proposing that PADEP did not support its conclusion by providing a sufficiently robust and well-developed record. Although here PADEP has adopted CTG requirements into specific permits versus relying on a regulation which incorporates the CTGs, the Commonwealth still relies on the CTGs equaling RACT, without a robust comparison with additional relevant information. Additionally, PADEP does not provide any documentation of an analysis to determine that RACT is fulfilled by existing source specific rules and the proposed concurrent revisions.

Therefore, EPA is proposing that it erred in its previous final action by approving PADEP's determination that particular emission limitations in the noted permits constitute RACT and we now propose disapproval of these components which we had approved in our December 14, 2020 final action.

B. Regulatory Revisions Related to VOC and NO_X RACT

The SIP revisions submitted by PADEP in the second August 13, 2018 SIP submittal, entitled ''Control of Volatile Organic Compound Emissions from Industrial Cleaning Solvents; General Provisions; Aerospace Manufacturing and Rework; Additional RACT Requirements for Major Sources of NO_X and VOCs,'' include: (1) the addition of 25 Pa. Code 129.63a (relating to the control of VOC from industrial cleaning solvents (ICS)); (2) amendments to 25 Pa. Code sections 121.1 and 129.51 (definitions and ''general'' provisions, respectively) in order to support the addition and implementation of 25 Pa. Code section 129.63a; (3) a correction to the VOC emission limit table in 25 Pa. Code section 129.73 (relating to aerospace manufacturing and re-work); and (4) amendments to 25 Pa. Code sections 129.96, 129.97, 129.99, and 129.100 to clarify certain requirements and to update the list of exemptions.

1. Addition of 25 Pa. Code Section 129.63a and Amendments to Sections 121.1 and 129.51

PADEP determined that the recommendations in EPA's 2006 ICS CTG are technically and economically feasible for sources in this source category and developed 25 Pa. Code section 129.63a for the purpose of implementing VOC RACT for affected industrial cleaning solvent sources in Pennsylvania. In EPA's December 14, 2020 final action, EPA approved this portion of the second August 13, 2018 SIP submittal based on the PADEP's determination that the 2006 ICS CTG is equal to RACT for the 2008 8-hour ozone NAAQs. Having reconsidered our prior approval, EPA is proposing that it erred in our prior full approval, and therefore we propose to revise the prior action to disapprove this portion of the submittal, as PADEP's analysis did not look beyond the CTG requirements.

Since the amendments to 25 Pa. Code sections 121.1 and 129.51 support the addition and implementation of section 129.63a, which EPA is now proposing to disapprove, the Agency is also proposing to disapprove the revisions made to 25 Pa. Code sections 121.1 and 129.51 we had previously approved into the SIP.

2. Amendments to 25 Pa. Code Sections 129.96, 129.97, 129.99, and 129.100

The second PADEP August 13, 2018 SIP submittal included amendments to 25 Pa. Code sections 129.96, 129.97, 129.99, and 129.100, to satisfy certain RACT requirements under both the 1997 and 2008 8-hour ozone NAAQS for specific source categories (also known as ''RACT II'').[8] These amendments update 25 Pa. Code sections 129.96(a) and (b) (relating to applicability) to revise the list of sources exempt from RACT II, because these source are already subject to a RACT requirement or RACT emission limitation, or both, that has been established elsewhere.[9] The applicability criteria in section 129.96(a) and (b) are revised in order to add reference to sections 129.52d, 129.52e and 129.74 (relating to control of VOC emissions from miscellaneous metal parts surface coating processes, miscellaneous plastic parts surface coating processes and pleasure craft surface coatings; control of VOC emissions from automobile and light-duty truck assembly coating operations and heavier vehicle coating operations; and control of VOC emissions from fiberglass boat manufacturing materials). Additionally, 25 Pa. Code sections 129.97(k)(1)(ii) and 129.99(i)(1)(ii) (relating to presumptive RACT requirements, RACT emission limitations and petition for alternative compliance schedule; and alternative RACT proposal and petition for alternative compliance schedule) were amended by adding the text ''or major VOC emitting facility'' for clarity. Section 129.100(a) (relating to compliance demonstration and recordkeeping requirements) was amended to add ''RACT'' in two places for clarity. The emission limits and substantive requirements of 25 Pa. Code sections 129.96, 129.97, 129.99, and 129.100 were not amended.

EPA has evaluated PADEP's amendments to 25 Pa. Code sections 129.96, 129.97, 129.99, and 129.100 and the Agency has made the preliminary determination that these clarifying amendments were appropriately approved in the prior action. The amendments made in this portion of the second SIP revision do not impact how PADEP determined that RACT was met by certain sources. Therefore, on reconsideration, EPA is not proposing to change our approval of PADEP's amendments to 25 Pa. Code sections 129.96, 129.97, 129.99, and 129.100 to disapproval.

III. Proposed Action

EPA is proposing to amend its prior full approval of PADEP's August 13, 2018 SIP submittals to a partial approval and partial disapproval. Specifically, EPA is proposing to retain approval of clarifying amendments to major source RACT regulations as well as a negative declaration for CTG RACT purposes. EPA is proposing disapproval of the remainder of both SIP submittals, including those related to CTGs and control of VOC emissions from industrial cleaning solvents. EPA is soliciting public comments on all of the issues discussed in this document. These comments will be considered before taking final action.

IV. Incorporation by Reference

In this document, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5 and as discussed in section II.B.2 of this preamble, EPA is proposing to incorporate by reference 25 Pa. Code sections 129.73, 129.96, 129.99, and 129.100. These measures were already incorporated by reference into the SIP under a previous approval (85 FR 80625, December 14, 2020). If this proposed disapproval is finalized, EPA does not intend to remove these amendments, but to retain them. EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region III Office (please contact the

[8] Pennsylvania's RACT II Rule applies statewide to existing major NO_X and/or VOC sources within the Commonwealth, except those subject to other Pennsylvania regulations, as specified in 25 Pa. Code 129.96(a) and (b).

[9] Other specific requirements of PADEP's two August 13, 2018 submittals and the rationale for EPA's proposed action are explained in EPA's previous notice of proposed rulemaking (NPRM) and will not be restated here. See 85 FR 12877, March 5, 2020.

person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Executive Orders 12866 and 13563: Regulatory Planning and Review

Under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011), this action is not a ''significant regulatory action'' and, therefore, is not subject to review by the Office of Management and Budget.

Paperwork Reduction Act

This rulemaking does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Regulatory Flexibility Act

This action merely proposes to disapprove state requirements as not meeting Federal requirements and imposes no additional requirements beyond those imposed by state law.

Accordingly, the Administrator certifies that this rulemaking will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Unfunded Mandates Reform Act

Because this rulemaking proposes to disapprove pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it 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).

Executive Order 13132: Federalism

This action also does not have federalism implications because it does not have substantial direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely proposes to disapprove a state requirement and does not alter the relationship or the distribution of power and responsibilities established in the CAA.

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

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 rulemaking 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).

Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

This rulemaking also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it proposes to disapprove a state rule.

Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

Because it is not a ''significant regulatory action'' under Executive Order 12866 or a ''significant energy action,'' this action is also not subject to Executive Order 13211 (66 FR 28355, May 22, 2001).

National Technology Transfer Advancement Act

In reviewing state submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. In this context, in the absence of a prior existing requirement for the state to use voluntary consensus standards (VCS), EPA has no authority to disapprove a state submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a state submission, to use VCS in place of a state submission that otherwise satisfies the provisions of the CAA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply.

Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 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. 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.'' 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.'' PADEP did not evaluate EJ considerations as part of its SIP submittals; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. EPA did not perform an EJ analysis and did not consider EJ in this action. Due to the nature of the action being taken here, this action is expected to have a neutral impact on the air quality of the affected area. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goal of E.O. 12898 of achieving environmental justice for people of color, low-income populations, and Indigenous peoples.

List of Subjects in 40 CFR Part 52

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

Adam Ortiz,

Regional Administrator, Region III.

[FR Doc. 2024–10370 Filed 5–16–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 282

[EPA–R07–UST–2023–0491; FRL–11446–01–R7]

Missouri: Final Approval of State Underground Storage Tank Program Revisions, Codification, and Incorporation by Reference

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Pursuant to the Resource Conservation and Recovery Act (RCRA or Act), the Environmental Protection Agency (EPA) is proposing to approve revisions to the State of Missouri's Underground Storage Tank (UST) program submitted by the Missouri Department of Natural Resources (MDNR). This action is based on the EPA's determination that these revisions satisfy all requirements needed for program approval. This action also

proposes to codify EPA's approval of Missouri's State program and incorporate by reference those provisions of the State regulations that we have determined meet the requirements for approval. The provisions will be subject to EPA's inspection and enforcement authorities RCRA and other applicable statutory and regulatory provisions.

DATES: Comments on this proposed rule must be received on or before June 17, 2024.

ADDRESSES: Submit comments, identified by EPA–R07–UST–2023–0491, by one of the following methods:

1. *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the on-line instructions for submitting comments.

2. *Email: drouare.douglas@epa.gov.*

Instructions: Direct your comments to Docket ID No. EPA–R07–UST–2023–0491. EPA's policy is that all comments received will be included in the public docket without change and may be available online at *https://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *https://www.regulations.gov,* or email. The Federal *https://www.regulations.gov* website is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *https://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and also with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties, and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. EPA encourages electronic submittals, but if you are unable to submit electronically, please reach out to the EPA contact person listed in the document for assistance. You can view and copy the documents that form the basis for this codification and associated publicly available materials either through *https://www.regulations.gov* or by contacting Douglas E. Drouare at (913) 551–7299 or *drouare.douglas@epa.gov.* Please call or email the contact listed above if you need access to material indexed but not provided in the docket.

FOR FURTHER INFORMATION CONTACT: Douglas E. Drouare, Tanks, Toxics, and Pesticides Branch, Land, Chemical, and Redevelopment Division, U.S. Environmental Protection Agency, Region 7, 11201 Renner Boulevard, Lenexa, Kansas 66219; telephone number: (913) 551–7299; email address: *drouare.douglas@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has explained the reasons for this action in the preamble to the direct final rule. For additional information, see the direct final rule published in the ''Rules and Regulations'' section of this **Federal Register**.

Authority: This proposed rule is issued under the authority of sections 2002(a), 7004(b), and 9004 of the Solid Waste Disposal Act, as amended, 42 U.S.C. 6912, 6991c, 6991d, and 6991e.

Dated: May 9, 2024.

Meghan McCollister,

Regional Administrator, EPA Region 7.

[FR Doc. 2024–10773 Filed 5–16–24; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 240513–0136]

RIN 0648–BM90

Fisheries of the Northeastern United States; Northeast Multispecies Fishery; Fishing Year 2024 Recreational Management Measures

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: This rulemaking proposes fishing year 2024 recreational management measures for Gulf of Maine (GOM) cod and GOM haddock. The measures are intended to ensure the recreational fishery achieves, but does not exceed, fishing year 2024 catch limits for GOM cod and GOM haddock. NMFS also announces that recreational measures for Georges Bank (GB) cod will remain unchanged in fishing year 2024.

DATES: Comments must be received by 5:00 p.m. EST on June 3, 2024.

ADDRESSES: A plain language summary of this proposed rule is available at *https://www.regulations.gov/docket/NOAA-NMFS-2024-0047.* You may submit comments on this document, identified by NOAA–NMFS–2024–0047, by the following method:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and enter NOAA–NMFS–2024–0047 in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *https://www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

To review **Federal Register** documents referenced in this proposed rule, you can visit: *https://www.fisheries.noaa.gov/management-plan/northeast-multispecies-management-plan.*

FOR FURTHER INFORMATION CONTACT: Mark Grant, Fishery Policy Analyst, (978) 281–9145.

SUPPLEMENTARY INFORMATION:

Background

Measures for the Gulf of Maine

The recreational fishery for GOM cod and GOM haddock is managed under the Northeast Multispecies Fishery Management Plan (FMP). The multispecies fishing year starts on May 1 and runs through April 30 of the following calendar year. The FMP sets sub-annual catch limits (sub-ACL) for the recreational fishery each fishing year for both stocks. These sub-ACLs are a fixed proportion of the overall catch limit for each stock. The FMP also includes proactive recreational accountability measures (AM) to prevent the recreational sub-ACLs from being exceeded and reactive AMs to correct the cause or mitigate the effects of an overage if one occurs.

The proactive AM provision in the FMP provides a process for the Regional Administrator, in consultation with the New England Fishery Management Council (Council), to develop recreational management measures for the upcoming fishing year to ensure that the recreational sub-ACL is achieved, but not exceeded. The provisions governing this action can be found in the FMP's implementing regulations at 50 CFR 648.89(f)(3).

The 2024 recreational sub-ACL for GOM cod, established by Framework Adjustment 63, is 192 metric tons (mt), remains the same as the 2023 recreational sub-ACL (87 FR 42375, July 15, 2022).

For fishing year 2024, Framework Adjustment 66 proposes a recreational sub-ACL for GOM haddock of 759 mt, which is a 4-percent reduction from the 2023 sub-ACL of 793 mt (89 FR 20412, March 22, 2024).

NMFS projected the 2024 recreational GOM cod and GOM haddock removals under several combinations of minimum sizes, slot limits, possession limits, and closed seasons using the 2024 GOM cod sub-ACL implemented by Framework Adjustment 63, the proposed 2024 GOM haddock sub-ACL in Framework Adjustment 66, and a peer-reviewed bio-economic model developed by NMFS's Northeast Fisheries Science Center. The bio-economic model considers measures for the two stocks in conjunction because cod are commonly caught while recreational participants are targeting haddock, linking the catch and effort for each stock to the other. The bio-economic model projected that status quo measures would adequately limit removals of GOM haddock in 2024, but the model also projected that the total GOM cod catch under status quo measures would exceed the 2024 sub-ACL.

For each of the sets of management measures, 100 simulations of the bio-economic model were conducted, and the number of simulations which yielded recreational mortality estimates under the sub-ACL was used as an estimate of the probability that the simulated set of measures will not result in an overage of the sub-ACL. Measures that do not result in model-estimated removals under the sub-ACL greater than 50 percent of the time are generally considered unsatisfactory. The results of initial bio-economic model runs were shared with the Council and its Recreational Advisory Panel (RAP) and Groundfish Oversight Committee for review at their January meetings.

The RAP, the Groundfish Committee, and the Council agreed on preferred measures and the Council formally recommended a suite of measures to NMFS on February 2, 2024. The Council recommended maintaining the GOM cod open season and 1-fish bag limit, while increasing the minimum fish size from 22 inches (55.9 centimeters (cm)) to 23 inches (58.4 cm); combined with maintaining the GOM haddock open season and increasing the minimum haddock fish size from 17 inches (43.2 cm) to 18 inches (45.7 cm) for private recreational vessels and increasing the GOM haddock bag limit from 10 fish to 15 fish for private recreational vessels. This change makes the recreational GOM haddock measures the same for all recreational vessels, rather than having different bag limits and minimum fish sizes for private vessels and for-hire vessels. The model projected that having different GOM haddock measures for private recreational vessels and for-hire vessels would not sufficiently constrain catch to the quota. The proposed measures are expected to adequately constrain recreational catch of GOM cod and GOM haddock based on the bio-economic model estimates. NMFS is proposing these Council-recommended measures for GOM cod and GOM haddock for fishing year 2024 (table 1).

TABLE 1—SUMMARY OF GULF OF MAINE STATUS QUO MEASURES AND PROPOSED MEASURES, WITH MODEL ESTIMATES OF CATCH AND THE PROBABILITY OF CATCH REMAINING BELOW THE SUB-ACLS

	GOM haddock							GOM cod				
	For hire possession limit	Private angler possession limit	For hire minimum size inches (cm)	Private angler minimum size inches (cm)	Open season	Projected catch (mt)	% Simulations under haddock sub-ACL	Possession limit	Minimum size inches (cm)	Open season	Projected catch (mt)	% Simulations under cod sub-ACL
Status Quo Measures	15	10	18	17	May 1–February 28/29 and April 1–April 30.	557.87	100	1	22 (55.9)	September 1–October 31.	200.21	34
Proposed Measures	15		18		May 1–February 28/29 and April 1–April 30.	517.68	100	1	23 (58.4)	September 1–October 31.	181.69	63

Status Quo for Georges Bank

This rule also announces that the current recreational measures for GB cod will remain in place for fishing year 2024. The Council reviewed the GB cod recreational catch and effort information provided by the Northeast Fisheries Science Center. This information shows that maintaining the status quo measures for GB cod would likely keep recreational catches close to the catch target of 113 mt in fishing year 2024.

Classification

NMFS is issuing this proposed rule pursuant to section 305(d) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) to carry out the FMP consistent with measures implemented in regulations at 50 CFR 648.89(f)(3). The NMFS Assistant Administrator has determined that this proposed rule is consistent with the Northeast Multispecies FMP and other applicable law, subject to further consideration after public comment.

Due to timing constraints resulting from the Council-recommend measures being finalized on January 31, 2024, NMFS is providing a 15-day comment period. This rulemaking proposes modifications to management measures for GOM cod and GOM haddock under existing NMFS authority to implement annual recreational fishing measures, in consultation with the Council. The Northeast multispecies fishing year begins on May 1 of each year and continues through April 30 of the following calendar year. Delaying final action on these proposed measures to allow for a longer comment period than the minimum 15-day amount allowed for by the Magnuson-Stevens Act would result in significant regulatory confusion for the industry and has the potential to negatively impact for-hire fishing business operations and bookings. Delayed implementation of measures may diminish the intended impact and increase the uncertainty of outcomes of measures and may potentially result in overages or overfishing. The changes to the GOM haddock measures are necessary to reduce bycatch of cod during the open season for GOM haddock. Delaying the change in the GOM haddock measures beyond May 1, 2024, is expected to increase cod bycatch above the levels projected by the bio-economic model and to raise the likelihood of an overage. GOM cod is overfished and was subject to overfishing in the most recent assessment which highlights the need for this action to be in place as close to the May 1, 2024, start of the fishing year as possible. The intended performance of Federal recreational measures also depends on the implementation of complementary state-waters measures by partner states. Delaying the promulgation of a final rule to allow more time for public comment may also impact the ability of states to implement complementary measures in a timely fashion, increasing regulatory confusion among private anglers and the for-hire industry, negatively impacting for-hire bookings, and introducing significant uncertainty into the performance of recreational measures. This rulemaking proposes changes that fall within the range of options discussed during a series of public meetings. Affected and other interested parties have already had opportunity to participate in the Council's process to develop this action, which provided extensive opportunity to comment about potential measures and their impacts.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration (SBA) that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities.

For Regulatory Flexibility Act (RFA) purposes only, NMFS established a small business size standard for businesses, including their affiliates, whose primary industry is fishing (see 50 CFR 200.2). A business primarily engaged in 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 less than $11.0 million for all its affiliated operations worldwide. A small for-hire recreational fishing business is defined as a firm with receipts of up to $11.0 million. Having different size standards for different types of fishing activities creates difficulties in categorizing businesses that participate in multiple fishing related activities. For purposes of this assessment, business entities have been classified into the SBA-defined categories based on which activity produced the highest percentage of average annual gross revenues from 2018–2022, the most recent 5-year period for which data are available. This classification is now possible because vessel ownership data are included in the Northeast permit database. The ownership data identify all individuals who own fishing vessels. Using this information, vessels can be grouped together according to common owners. Each of the resulting groups was treated as a single fishing business for purposes of this analysis. Revenues are summed across all vessels in a group and the activities that generate those revenues form the basis for determining whether the entity is a large or small business. As the for-hire owner is permitted and required to comply with these measures and can be held liable under the law for violations of the proposed regulations, for-hire business entities are considered directly affected in this analysis. Private anglers are not considered ''entities'' under the RFA.

For-hire fishing businesses are required to obtain a Federal charter/party Northeast multispecies fishing permit in order to carry passengers to catch Northeast multispecies including GOM cod and GOM haddock. Limited access permit holders may also take passengers for-hire but are not allowed to hold any open access permits. Thus, the affected businesses entities of concern are businesses that hold Federal Northeast multispecies Limited Access permits or for-hire fishing permits (Category I). While all of these business entities could be affected by changes in recreational fishing restrictions, not all entities actively participate in a given year. Those who actively participate (*i.e.,* report catch) would be the group of business entities that are affected by the regulations. Latent fishing power (in the form of unfished permits) has the potential to alter the impacts on a fishery, but it is not possible to predict how many of these latent business entities will participate in this fishery in fishing year 2024. The Northeast Federal permits database indicates that a total of 1,314 vessels held a Northeast multispecies Limited Access or for-hire fishing permit in 2022 (the most recent full year of available data). Of these 1,314 vessels, only 154 actively participated in the for-hire Atlantic cod and haddock fishery in calendar year 2022 (*i.e.,* reported catch of cod or haddock). NMFS used these participants to analyze the potential economic impact of these regulations.

Using vessel ownership information and vessel trip report data, NMFS determined that the 154 for-hire vessels actively participating in the fishery are owned by 142 unique fishing business entities. The majority of the 142 fishing businesses were solely engaged in for-hire fishing, but some also earned revenue from commercial shellfish and/or finfish fishing. The highest percentage of annual gross revenues for all but 12 of the fishing businesses was from for-hire fishing.

Average annual gross revenue estimates calculated from the most recent 5 years (2018–2022) indicate that none of the 142 fishing business entities

had annual receipts of more than $11.0 million from all of their fishing activities (*i.e.,* for-hire, shellfish, and finfish). Therefore, all of the affected fishing business entities are considered ''small'' by the SBA size standards, and thus this action will not disproportionately affect small versus large for-hire business entities. The proposed measures are expected to have a negative, but negligible, effect on small entities because they are expected to reduce GOM cod and GOM haddock catch and reduce overall trips, compared to status quo measures. The proposed measures for GOM cod and GOM haddock would lead to more restrictive harvest opportunities for for-hire anglers that balance the need for additional restrictions with opportunities to target these stocks. This action is not expected to have a significant or substantial effect on small entities. Under the proposed action, small entities would not be placed at a competitive disadvantage relative to large entities, and the regulations would not substantially reduce profit for any small entities. Based on these conclusions, 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.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Recordkeeping and reporting requirements.

Dated: May 13, 2024.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, NMFS proposes to amend 50 CFR part 648 as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 648.89, revise table 1 to paragraph (b)(1) and table 2 to paragraph (c)(1)(i) to read as follows:

§ 648.89 Recreational and charter/party vessel restrictions.

* * * * *

(b) * * *

(1) * * *

TABLE 1 TO PARAGRAPH (b)(1)

Species	Charter/party minimum size		Private minimum size		Maximum size	
	Inches	cm	Inches	cm	Inches	cm
Cod:						
Inside GOM Regulated Mesh Area [1]	23	58.4	23	58.4	N/A	N/A
Outside GOM Regulated Mesh Area [1]	23	58.4	23	58.4	N/A	N/A
Haddock:						
Inside GOM Regulated Mesh Area [1]	18	45.7	18	45.7	N/A	N/A
Outside GOM Regulated Mesh Area [1]	18	45.7	18	45.7	N/A	N/A
Pollock	19	48.3	19	48.3	N/A	N/A
Witch Flounder (gray sole)	14	35.6	14	35.6	N/A	N/A
Yellowtail Flounder	13	33.0	13	33.0	N/A	N/A
American Plaice (dab)	14	35.6	14	35.6	N/A	N/A
Atlantic Halibut	41	104.1	41	104.1	N/A	N/A
Winter Flounder (black back)	12	30.5	12	30.5	N/A	N/A
Redfish	9	22.9	9	22.9	N/A	N/A

[1] GOM Regulated Mesh Area specified in § 648.80(a).

* * * * *

(c) * * *

(1) * * *

(i) * * *

TABLE 2 TO PARAGRAPH (c)(1)(i)

Stock	Open season	Possession limit	Closed season
GB Cod	September 1–April 30; May 1–31	5	June 1–August 31.
GOM Cod	September 1–October 31	1	May 1–August 31; November 1–April 30.
GB Haddock	All Year	Unlimited	N/A.
GOM Haddock	May 1–February 28 (or 29); April 1–30	15	March 1–March 31.
GB Yellowtail Flounder	All Year	Unlimited	N/A.
SNE/MA Yellowtail Flounder	All Year	Unlimited	N/A.
CC/GOM Yellowtail Flounder	All Year	Unlimited	N/A.
American Plaice	All Year	Unlimited	N/A.
Witch Flounder	All Year	Unlimited	N/A.
GB Winter Flounder	All Year	Unlimited	N/A.
GOM Winter Flounder	All Year	Unlimited	N/A.
SNE/MA Winter Flounder	All Year	Unlimited	N/A.
Redfish	All Year	Unlimited	N/A.
White Hake	All Year	Unlimited	N/A.
Pollock	All Year	Unlimited	N/A.

TABLE 2 TO PARAGRAPH (c)(1)(I)—Continued

Stock	Open season	Possession limit	Closed season
N Windowpane Flounder	CLOSED	No retention	All Year.
S Windowpane Flounder	CLOSED	No retention	All Year.
Ocean Pout	CLOSED	No retention	All Year.
Atlantic Halibut	See paragraph (c)(3)		
Atlantic Wolffish	CLOSED	No retention	All Year.

* * * * *

[FR Doc. 2024–10849 Filed 5–16–24; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 89, No. 97
Friday, May 17, 2024

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 will submit the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13 on or after the date of publication of this notice. Comments are requested regarding: (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding these information collections are best assured of having their full effect if received by June 17, 2024. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

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.

National Agricultural Statistics Service (NASS)

Title: Aquaculture Survey—Substantive Change.

OMB Control Number: 0535–0150.

Summary of Collection: The primary objective of the National Agricultural Statistics Service is to prepare and issue State and national estimates of crop and livestock production, prices, and disposition. The Aquaculture Surveys program produces estimates at the national level on both trout and catfish. Survey results are used by government agencies and others in planning farm programs.

The trout survey includes sales (dollars, pounds, and quantities), percent of product sold by outlet at the point of first sale, distribution (dollars, pounds, and quantities) of fish raised for release into open waters, and losses. The catfish surveys include inventory counts, water surface acreage used for production and sales (dollars, pounds, and quantities).

The National Agricultural Statistics Service (NASS) is requesting a substantive change to the Aquaculture Survey information collection request (OMB No. 0535–0150) for trout program changes. Every five years NASS conducts a program review following the completion of the Census of Agriculture. The program changes balance resources across all of the programs included in the annual estimating program, which represents over 400 individual reports across multiple Information Collection Requests (ICRs). This substantive change is to accommodate the trout program changes that affect this ICR. The methodology, publication dates, burden and data collection plan do not change as result of these program changes. The changes to these surveys will not affect burden hours.

Need and Use of the Information: Survey results are used by members of the Cooperative Extension System and the National Sea Grant College Program who research and work in aquaculture. The information is used to analyze changing trends in the number of commercial operations and production levels by State, as well as to demonstrate the growing importance of aquaculture to officials of federal and State government agencies who manage and direct policy for programs in agriculture and natural resources. Extension specialists use the data to demonstrate the impact of educational programs and other efforts to assist in developing economically viable aquaculture operations. The type of information collected and reported provides extension educators and research scientists with data that indicate important areas that require special educational and/or research efforts, such as causes for fish loss and pond inventories of fish of various sizes.

Description of Respondents: Farms; businesses or other for-profits.

Number of Respondents: 2,950.

Frequency of Responses: Reporting: on occasion; annually.

Total Burden Hours: 551.

National Agricultural Statistics Service (NASS)

Title: Bee and Honey Survey—Substantive Change.

OMB Control Number: 0535–0153.

Summary of Collection: The primary functions of the National Agricultural Statistics Service (NASS) are to prepare and issue State and national estimates of crop and livestock production, disposition, and prices, and to collect information on related environmental and economic factors. Crop and livestock statistics help maintain a stable economic atmosphere and reduce risk for production, marketing, and distribution operations. Modern agriculture increasingly calls upon NASS to supply reliable, timely, and detailed information through its commodity estimation program. As part of this function, estimates are made for honey production, stocks, and prices.

The National Agricultural Statistics Service (NASS) is requesting a substantive change to the Bee and Honey Survey information collection request (OMB No. 0535–0153) for honey program changes. Every five years NASS conducts a program review following the completion of the Census of Agriculture. The program changes balance resources across all of the programs included in the annual estimating program, which represents over 400 individual reports across multiple Information Collection Requests (ICRs). This substantive change is to accommodate the honey program changes that affect this ICR. The methodology, publication dates,

burden and data collection plan do not change as result of these program changes. The changes to these surveys will not affect burden hours.

Need and Use of the Information: The bee and honey surveys are conducted in all States. These surveys collect data on the number of colonies each operation has, the amount of honey produced and the amount of honey stocks available for sale.

The Agricultural Research Service (ARS), State-level apiarists, and agricultural colleges throughout the U.S. use NASS bee and honey data to administer their honeybee research programs. Current research projects at ARS focus on colony collapse disorder, parasites, Africanized honeybees, foul brood disease, food safety and inspection (including honey), and other topics.

The Agricultural Marketing Service (AMS) uses NASS honey production data as control data for the administration of the research and promotion programs. The Honey Packers and Importers Research, Promotion, Consumer Education, and Industry Information Order (Order) [7 CFR part 1212] is authorized by the Commodity Promotion, Research, and Information Act of 1996 (1996 Act) [7 U.S.C. 7411–7425]. Under the Order, assessments are collected on honey and honey products packed or imported into the 50 states, Puerto Rico, and the District of Columbia. The funds collected are used by the National Honey Board for research and development, advertising and promotion of honey and honey products, consumer education, and industry information, under AMS supervision. The National Honey Board administers the research and promotion programs and reimburses the Federal government for the costs incurred in implementing and administering the program.

The Economic Research Service (ERS) uses NASS honey data to construct U.S. and per capita caloric sweetener consumption estimates. The data are used in the Sugar and Sweeteners Yearbook tables provided by ERS. The data are also utilized in the Situation and Outlook Report and the Food Consumption series, which are mandated by Congress. Economic data published in the Honey report is also used to prepare valuations related to pollinators.

The Farm Service Agency (FSA) uses NASS honey production data as source data. The Farm Security and Rural Investment Act of 2002 provides that the FSA administer the nonrecourse marketing assistance loan and loan deficiency payment (LDP) program for honey. The honey nonrecourse marketing assistance loan and LDP program provides eligible honey producers with two forms of Federal assistance. The program helps to stabilize America's honey industry and ensure the wellbeing of agriculture in the United States. Nonrecourse marketing assistance loans are administered by FSA on behalf of the Commodity Credit Corporation (CCC). The Food, Conservation, and Energy Act of 2008 (2008 Farm Bill) authorized the Emergency Assistance for Livestock, Honey Bees, and Farm-Raised Fish Program (ELAP). ELAP assistance covers some species, loss conditions, and losses that are not eligible for other disaster assistance programs, including colony collapse disorder. The Agriculture Improvement Act of 2018 (the 2018 Farm Bill) authorized the use of Commodity Credit Corporation funds for the Emergency Assistance for Livestock, Honeybees and Farm-Raised Fish Program (ELAP). ELAP provides emergency assistance to eligible producers of livestock, honeybees and farm-raised fish. It covers losses due to an eligible adverse weather or loss condition, including blizzards and wildfires, as determined by the Secretary of Agriculture. ELAP covers losses that are not covered under other disaster assistance programs authorized by the 2014 Farm Bill, such as the Livestock Forage Disaster Program (LFP) and the Livestock Indemnity Program (LIP).

The Risk Management Agency (RMA) is now offering a pilot insurance program for apiculture. This pilot program uses rainfall and vegetation greenness indices to estimate local rainfall and plant health, allowing beekeepers to purchase insurance protection against production risks. The program will use a 5-year average honey yield at the state level and the annual average honey price at the national level, both based on NASS data, to determine insurance payments.

The Pollinator Health Task Force uses data from the Honey Bee Colonies report to monitor honeybee colony losses during winter. Their goal, as laid out in the Pollinator Research Action Plan, is to reduce these losses to no more than 15 percent within 10 years. The Food and Drug Administration provided some background information on the importance of honeybees in an article they published in July 2018. ''Honey bees are not native to the New World. Most crops grown in the U.S. are not New World natives either. Both the crops and the bees evolved together in other areas of the globe, and were brought here by European settlers. Information suggests that the first honeybee colonies arrived in the Colony of Virginia from England early in 1622.

Today, the commercial production of more than 90 crops relies on bee pollination. Of the approximately 3,600 bee species that live in the U.S., the European honeybee2 (scientific name Apis mellifera) is the most common pollinator, making it the most important bee to domestic agriculture. About one-third of the food eaten by Americans comes from crops pollinated by honey bees, including apples, melons, cranberries, pumpkins, squash, broccoli, and almonds, to name just a few. Without the industrious honey bee, American dinner plates would look quite bare.''

Description of Respondents: Businesses or other for-profits; Farms.

Number of Respondents: 12,225.

Frequency of Responses: Quarterly; Annually.

Total Burden Hours: 7,920.

National Agricultural Statistics Service (NASS)

Title: Agricultural Resource Management Phases 1 & 2 and Chemical Use Surveys—Substantive Change.

OMB Control Number: 0535–0218.

Summary of Collection: General authority for these data collection activities is granted under U.S. Code Title 7, Section 2204 which specifies that ''The Secretary of Agriculture shall procure and preserve all information concerning agriculture which he can obtain . . . by the collection of statistics . . .''. The primary objective of the National Agricultural Statistics Service (NASS) is to provide data users with timely and reliable agricultural production and economic statistics, as well as environmental and specialty agricultural related statistics. To accomplish this objective, NASS relies on the use of diverse surveys that show changes within the farming industry over time.

The National Agricultural Statistics Service (NASS) is requesting a substantive change to the Aquaculture Survey information collection request (OMB No. 0535–0150) for vegetable chemical use program changes. Every five years NASS conducts a program review following the completion of the Census of Agriculture. The program changes balance resources across all of the programs included in the annual estimating program, which represents over 400 individual reports across multiple Information Collection Requests (ICRs). This substantive change is to accommodate the trout program changes that affect this ICR.

The methodology, publication dates, burden and data collection plan do not change as result of these program changes. The changes to these surveys will not affect burden hours.

Included with this change request are (1) Addition of the Arizona Enterprise Version of the Vegetable Chemical Use Survey that should have been added earlier, and

(2) One version of the ARMS 2 Wheat Production Practices Report. The one version will be used in lieu of three versions (winter, Durum, and other spring wheat) submitted earlier.

Need and Use of the Information: ARMS is the only annual source of whole farm information available for objective evaluation of many critical issues related to agriculture and the rural economy. This issues that will be addressed in this request are: input usage, production practices, and chemical use. Without these data, decision makers cannot analyze and report on critical issues that affect farms and farm households when pesticide regulatory actions are being considered.

Description of Respondents: Farms; Business or other for-profit.

Number of Respondents: 416,150.

Frequency of Responses: Reporting: Quarterly; Semi-annually; Monthly; Annually.

Total Burden Hours: 52,147.

Levi S. Harrell,

Departmental Information Collection Clearance Officer.

[FR Doc. 2024–10790 Filed 5–16–24; 8:45 am]

BILLING CODE 3410–20–P

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 required 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 June 17, 2024 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 particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

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Farm Service Agency

Title: Volunteer Programs.

OMB Control Number: 0560–0232.

Summary of Collection: Section 1526 of the Food and Agriculture Act of 1981 (7 U.S.C. 2272) permits the Secretary of Agriculture to establish a program to use volunteers to perform a wide range of activities to carry out the programs of or supported by the Department of Agriculture (USDA). Each USDA agency is granted the authority to establish programs designed to provide educationally related work assignments for students in non-pay status. USDA, Departmental Regulation 4230–1 requires documentation of service performed without compensation by persons who do not receive Federal appointment. For this requirement, the information collection request is necessary to continue implementation of the programs, which allows the Farm Service Agency (FSA) and Risk Management Agency (RMA) to use volunteers to perform a wide range of activities to carry out the programs of or supported by the Agency.

Need and Use of the Information: Applicants who are accepted in the program will complete the ''Service Agreement and Attendance Record.'' FSA and RMA will use the reported information to respond to request for information on volunteers from the USDA Office of Human Resources Management. FSA Human Resource is responsible for determining how to document volunteer appointments. If the information were not collected for each volunteer, FSA and RMA would be unable to document service performed without compensation by persons in the program if this information were not collected for each volunteer.

Description of Respondents: Individuals or households.

Number of Respondents: 20.

Frequency of Responses: Reporting: Annually.

Total Burden Hours: 20.

Rachelle Ragland-Greene,

Acting Departmental Information Collection Clearance Officer.

[FR Doc. 2024–10865 Filed 5–16–24; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2023–0079]

Spotted Lanternfly Cooperative Control Program; Programmatic Environmental Assessment and Finding of No Significant Impact

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has prepared a programmatic environmental assessment and finding of no significant impact relative to the Spotted Lanternfly Cooperative Control Program in the conterminous United States. The environmental assessment documents our review and analysis of environmental impacts associated with the Spotted Lanternfly Cooperative Control Program. Based on its finding of no significant impact, the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

FOR FURTHER INFORMATION CONTACT: Mr. Matthew Travis, Spotted Lanternfly National Policy Manager, PPQ, APHIS, Emergency and Domestic Programs, 4700 River Road, Unit 133, Riverdale, MD 20737–1238; telephone: (580) 240–5394; email: *Matthew.A.Travis@usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

The spotted lanternfly (SLF), *Lycorma delicatula,* an invasive species native to Asia, is a destructive pest that in large numbers can cause significant damage to critical habitat and economically important plants. The U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS) proposed to control SLF to slow the spread of this

invasive insect in the conterminous United States wherever outbreaks are detected.

SLF infestation has led to crop loss, agriculture exportation problems, and increased management costs. APHIS has concerns with the potential for long-distance movement of SLF within the United States, and the continued risk of SLF introduction from other countries. Additionally, APHIS acknowledges that the environmental and socioeconomic damage to SLF-affected regions can be substantial.

On November 9, 2023, we published in the **Federal Register** (88 FR 77259–77260, Docket No. APHIS–2023–0079) a notice [1] in which we announced the availability, for public review and comment, of a programmatic environmental assessment (ProEA) that examined the potential environmental impacts associated with the SLF cooperative control program. In our analysis, APHIS found that an adaptive pest management approach that combines quarantine, chemical treatments, and pest survey is the preferred alternative to address the potential environmental impact of a SLF outbreak.

We solicited comments on the ProEA for 30 days ending December 11, 2023. We received two comment submissions by that date. A commenter questioned why Alaska and Hawaii were excluded from the ProEA, citing a map for the possible host range of SLF that indicated it could become established in Alaska. The ProEA was limited to the conterminous United States based on information that possible introduction of SLF into Alaska was not imminent. However, should SLF become established in Alaska, a supplemental EA will be prepared. The same commenter also raised a concern with a perceived lack of information and analyses on the economic impact of an SLF outbreak in the draft ProEA. Finally, another commenter agreed with APHIS that SLF is a destructive pest. The comments that we received, and APHIS' responses to the comments, are presented in our finding of no significant impact (FONSI) (see supporting documents).

In this document, we are advising the public of our FONSI on the implementation of the adaptive management alternative for the SLF program. The finding, which is based on the results of the analysis in the final ProEA, reflects our determination that under this alternative, the methods used to exclude, detect, prevent, and control SLF infestations will not have a significant impact on the quality of the human environment.

The ProEA and FONSI may be viewed on the *regulations.gov* website or in our reading room (see **ADDRESSES** above for a link to *regulations.gov* and information on the location and hours of the reading room). You may also request paper copies of the ProEA and FONSI by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the title of the ProEA when requesting copies.

The ProEA and FONSI have been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Done in Washington, DC, this 3rd day of May 2024.

Michelle Wenberg,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2024–10648 Filed 5–16–24; 8:45 am]

BILLING CODE 3410–34–P

[1] To view the notice, the supporting documents, and the comments we received, go to *www.regulations.gov,* and enter APHIS–2023–0079 in the Search field.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2024–0008]

Retail Exemptions Adjusted Dollar Limitations

AGENCY: Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA).

ACTION: Notice.

SUMMARY: FSIS is announcing the dollar limitations on the amount of meat and meat products and poultry and poultry products that a retail store can sell to hotels, restaurants, and similar institutions without disqualifying itself for exemption from Federal inspection requirements.

DATES: *Applicable* June 17, 2024.

FOR FURTHER INFORMATION CONTACT: Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Mailstop 3758, South Building, Washington, DC 20250–3700; 202–720–5046.

SUPPLEMENTARY INFORMATION:

Background

The Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*) provide a comprehensive statutory framework to ensure that meat and meat products and poultry and poultry products prepared for commerce are wholesome, not adulterated, and properly labeled and packaged. Statutory provisions requiring inspection of the processing of meat and meat products and poultry and poultry products do not apply to operations of types traditionally and usually conducted at retail stores and restaurants in regard to products offered for sale to consumers in normal retail quantities (21 U.S.C. 661(c)(2) and 454(c)(2)). FSIS' regulations (9 CFR 303.1(d) and 381.10(d)) elaborate on the conditions under which requirements for inspection do not apply to retail operations involving the preparation of meat and meat products and the processing of poultry and poultry products.

Sales to Hotels, Restaurants, and Similar Institutions

Under the aforementioned regulations, sales to hotels, restaurants, and similar institutions (other than household consumers) disqualify a retail store from exemption if the retail product sales of amenable products exceed either of two maximum limits: 25 percent of the dollar value of the total retail product sales or the calendar year retail dollar limitation set by the FSIS Administrator. The retail dollar limitation is adjusted automatically during the first quarter of the year if the Consumer Price Index (CPI), published by the Bureau of Labor Statistics, shows an increase or decrease of more than $500 in the price of the same volume of product for the previous year. FSIS publishes a notice of the adjusted retail dollar limitations in the **Federal Register**. (See 9 CFR 303.1(d)(2)(iii)(*b*) and 381.10(d)(2)(iii)(*b*).)

The CPI for 2023 reveals an annual average price increase for meat and meat products of 2.07 percent, an average annual price increase for Siluriformes fish and fish products of 0.31 percent, and an annual average price increase for poultry and poultry products of 3.10 percent.[1] [2] [3] When rounded to the

[1] U.S. Bureau of Labor Statistics (BLS), Consumer Price Index for All Urban Consumers (CPI–U): Meats in U.S. city average, all urban consumers, not seasonally adjusted [Series ID CUUR0000SAF11211], accessed on February 8, 2024.

[2] BLS, CPI–U: Fish and seafood in U.S. city average, all urban consumers, not seasonally

Continued

nearest $100 dollar, the retail dollar limitation for meat and meat products, including Siluriformes fish and fish products, increased by $2,000 [4] and the retail dollar limitation for poultry and poultry products increased by $2,200.[5] In accordance with 9 CFR 303.1(d)(2)(iii)(*b*) and 381.10(d)(2)(iii)(*b*), because the retail dollar limitations for meat and meat products and poultry and poultry products increased by more than $500, FSIS is increasing the dollar limitation on sales to hotels, restaurants, and similar institutions to $100,900 for meat and meat products and to $74,200 for poultry and poultry products for calendar year 2024.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: *https://www.fsis.usda.gov/federal-register.*

FSIS will also announce and provide a link to this **Federal Register** publication through the FSIS *Constituent Update,* which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS can provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *https://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

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(1) Mail: U.S. Department of Agriculture Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410;

(2) Fax: (833) 256–1665 or (202) 690–7442; or

(3) Email: *program.intake@usda.gov.*

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Paul Kiecker,

Administrator.

[FR Doc. 2024–10918 Filed 5–16–24; 8:45 am]

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adjusted [Series ID CUUR0000SEFG], accessed on February 8, 2024.

[3] BLS, CPI–U: Poultry in U.S. city average, all urban consumers, not seasonally adjusted [Series ID CUUR0000SEFF],'' accessed on February 8, 2024.

[4] The base value for meat and meat products in 2023 was $98,910 rounded to the nearest $100 dollar to $98,900. The base value included $95,940 for meat and meat products and $2,970 to account for Siluriformes fish and fish products. The meat and meat products prices increased by 2.07 percent, or $1,986 ($95,940 × 0.0207 = $1,986), during 2023. The Siluriformes fish and fish products prices increased by 0.31 percent, or $9 ($2,970 × 0.0031 = $9), during 2023. Combined, the value for meat and meat products that includes Siluriformes fish and fish products increased by $1,995 ($1,986 + $9). Since this change is more than $500, the retail dollar limitation is adjusted to $100,905 [($95,940 + $1,986) + ($2,970 + $9) = $100,905, which is rounded to $100,900].

[5] The base value for poultry and poultry products in 2023 was $71,984 rounded to the nearest $100 dollar to $72,000. The poultry and poultry products prices increased by 3.10 percent, or $2,232 ($71,984 x 0.0310 = $2,232), during 2023. Since this change is more than $500, the retail dollar limitation is adjusted to $74,200 ($71,984 + $2,232 = $74,216, which is rounded to $74,200).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–877, A–570–064, C–533–878, C–570–065]

Stainless Steel Flanges From the People's Republic of China and India: Final Results of Changed Circumstances Reviews and Revocation of the Antidumping and Countervailing Duty Orders, in Part

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) is issuing the final results of changed circumstances reviews (CCRs) of the antidumping duty and countervailing duty orders on stainless steel flanges from the People's Republic of China (China) and India to revoke the orders, in part, with respect to stainless steel flanges produced to specification SAE J518 (or its international equivalent, ISO 6162).

DATES: Applicable May 17, 2024.

FOR FURTHER INFORMATION CONTACT: Sun Cho, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6458.

SUPPLEMENTARY INFORMATION:

Background

On March 29, 2024, Commerce published its initiation and preliminary results in the CCRs on stainless steel flanges from China and India,[1] in which Commerce found that changed circumstances warranted revocation of the *Orders,*[2] in part, with respect to

[1] *See Stainless Steel Flanges from the People's Republic of China and India: Initiation and Preliminary Results of Changed Circumstances Reviews and Intent to Revoke the Antidumping and Countervailing Duty Orders, in Part,* 89 FR 22120 (March 29, 2024) (*Preliminary Results*).

[2] *See Stainless Steel Flanges from the People's Republic of China: Countervailing Duty Order,* 83 FR 26006 (June 5, 2018) (*China CVD Order*); *Stainless Steel Flanges from the People's Republic of China: Antidumping Duty Order,* 83 FR 37468 (August 1, 2018) (*China AD Order*); *Stainless Steel Flanges from India: Antidumping Duty Order,* 83 FR 50639 (October 9, 2018) (*India AD Order*); and *Stainless Steel Flanges from India: Countervailing Duty Order,* 83 FR 50336 (October 5, 2018) (*India CVD Order*) (collectively, *Orders*).

certain stainless steel flanges that are produced to specification SAE J518 (or its international equivalent, ISO 6162), and not to any other specification. Commerce provided interested parties with the opportunity to comment and request a public hearing regarding the *Preliminary Results.* Commerce did not receive any comments from interested parties.

Final Results of Changed Circumstances Reviews and Revocation of the Orders, in Part

We conducted these CCRs based on a request from Anchor Fluid Power (Anchor), an importer of stainless steel flanges. Anchor requested that Commerce issue the final results of these CCRs on an expedited basis (*i.e.,* within 45 days of publication of the *Preliminary Results* in the **Federal Register**) pursuant to 19 CFR 351.216(e) or by May 13, 2024.[3] Because no party submitted comments opposing the *Preliminary Results* of these CCRs, and the record contains no other information or evidence that calls into question the *Preliminary Results,* Commerce determines, pursuant to sections 751(d)(1) and 782(h) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.222(g), that there are changed circumstances that warrant revocation of the *Orders,* in part, with respect to the stainless steel flanges subject to Anchor's request. Consequently, there is no decision memorandum accompanying this notice.

Specifically, because producers accounting for substantially all of the production of the domestic like product to which the *Orders* pertain have not expressed interest in maintaining the relief provided by the *Orders* with respect to certain stainless steel flanges, as described below, Commerce is revoking the *Orders,* in part, with respect to the following product:

The stainless steel flanges produced to specification SAE J518 (or its international equivalent, ISO 6162) and not to any other specification.

The revised scope for the *Orders* is below.

Scope of the Orders

The scope of the *Orders* covers certain forged stainless steel flanges, whether unfinished, semi-finished, or finished (certain forged stainless steel flanges). Certain forged stainless steel flanges are generally manufactured to, but not limited to, the material specification of ASTM/ASME A/SA182 or comparable domestic or foreign specifications. Certain forged stainless steel flanges are made in various grades such as, but not limited to, 304, 304L, 316, and 316L (or combinations thereof). The term ''stainless steel'' used in this scope refers to an alloy steel containing, by actual weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with or without other elements. Unfinished stainless steel flanges possess the approximate shape of finished stainless steel flanges and have not yet been machined to final specification after the initial forging or like operations. These machining processes may include, but are not limited to, boring, facing, spot facing, drilling, tapering, threading, beveling, heating, or compressing. Semi-finished stainless steel flanges are unfinished stainless steel flanges that have undergone some machining processes.

The scope includes six general types of flanges. They are: (1) weld neck, generally used in butt-weld line connection; (2) threaded, generally used for threaded line connections; (3) slip-on, generally used to slide over pipe; (4) lap joint, generally used with stub-ends/butt-weld line connections; (5) socket weld, generally used to fit pipe into a machine recession; and (6) blind, generally used to seal off a line. The sizes and descriptions of the flanges within the scope include all pressure classes of ASME B16.5 and range from one-half inch to twenty-four inches nominal pipe size. Specifically excluded from the scope of the *Orders* are cast stainless steel flanges. Cast stainless steel flanges generally are manufactured to specification ASTM A351.

Also excluded from the scope are stainless steel flanges produced to specification SAE J518 (or its international equivalent, ISO 6162) and not to any other specification.

The country of origin for certain forged stainless steel flanges, whether unfinished, semi-finished, or finished is the country where the flange was forged. Subject merchandise includes stainless steel flanges as defined above that have been further processed in a third country. The processing includes, but is not limited to, boring, facing, spot facing, drilling, tapering, threading, beveling, heating, or compressing, and/or any other processing that would not otherwise remove the merchandise from the scope of the *Orders* if performed in the country of manufacture of the stainless steel flanges.

Merchandise subject to the *Orders* is typically imported under headings 7307.21.1000 and 7307.21.5000 of the Harmonized Tariff Schedule of the United States (HTSUS). While HTSUS subheadings and ASTM specifications are provided for convenience and customs purposes, the written description of the scope is dispositive.

Application of the Final Results of These Reviews

Anchor requested that Commerce apply the final results of these reviews retroactively. Commerce has discretion to determine the applicable date of the determination pursuant to section 751(d)(3) the Act, which provides that ''{a} determination under this section to revoke an order . . . shall apply with respect to unliquidated entries of the subject merchandise which are entered, or withdrawn from warehouse, for consumption on or after the date determined by the administering authority.'' Commerce also notes that substantially all of the domestic industry, which is in support of the partial revocation, also agrees with applying the partial revocation retroactively. Because Anchor did not provide a specific date as to which it believes the final results should retroactively apply, Commerce is applying the partial revocation to unliquidated entries of merchandise subject to the CCRs that were entered or withdrawn from warehouse, for consumption, on or after the day following the last day of the period covered by the most recently-completed administrative review of each of the *Orders,* and are not already subject to automatic liquidation instructions.

Instructions to U.S. Customs and Border Protection (CBP)

Because we determine there are changed circumstances that warrant the revocation of the *Orders,* in part, we will instruct CBP to liquidate without regard to antidumping and countervailing duties, and to refund any estimated antidumping and countervailing duties on all unliquidated entries of the merchandise covered by this partial revocation, effective as follows: January 1, 2022 (*India CVD Order*); October 1, 2022 (*India AD Order*); January 1, 2023 (*China CVD Order*); and August 1, 2023 (*China AD Order*).

Commerce intends to issue instructions to CBP no earlier than 35 days after the date of publication of these final results of CCRs in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the 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).

[3] *See* Anchor's Letter, ''Request to Expedite Final Results of Changed Circumstances Review,'' dated April 17, 2024.

Administrative Protective Order

This notice serves as a final reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return 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 sanctionable violation.

Notification to Interested Parties

This notice is published in accordance with sections 751(b)(1) and 777(i) of the Act, 19 CFR 351.216, 19 CFR 351.221(c)(3), and 19 CFR 351.222.

Dated: May 10, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2024–10789 Filed 5–16–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–847]

Heavy-Walled Rectangular Welded Carbon Steel Pipes and Tubes From Mexico: Amended Final Results of Antidumping Duty Administrative Review; 2021–2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) is amending the final results of the administrative review of the antidumping duty (AD) order on heavy-walled rectangular welded carbon steel pipes and tubes (HWR pipes and tubes) from Mexico to correct a ministerial error. The period of review (POR) is September 1, 2021, through August 31, 2022.

DATES: Applicable May 17, 2024.

FOR FURTHER INFORMATION CONTACT: David Crespo or Taylor Hatley, 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) 482–3693 or (202) 482–4886, respectively.

SUPPLEMENTARY INFORMATION:

Background

On April 9, 2024, Commerce published in the **Federal Register** the *Final Results* of the 2021–2022 administrative review of the AD order on HWR pipes and tubes from Mexico.[1] On April 4, 2024, Commerce disclosed its calculations and provided interested parties with the opportunity to submit ministerial error comments.[2] On April 9, 2024, Productos Laminados de Monterrey S.A. de C.V (Prolamsa), a mandatory respondent in this review, timely submitted a ministerial error allegation.[3] No other interested party submitted a ministerial error allegation or rebutted Prolamsa's ministerial error allegation. We are amending the *Final Results* to correct the ministerial error raised by Prolamsa.

Legal Framework

Section 751(h) of the Tariff Act of 1930, as amended (the Act), defines a ''ministerial error'' as including ''errors in addition, subtraction, or other arithmetic function, clerical errors resulting from inaccurate copying, duplication, or the like, and any other unintentional error which the administering authority considers ministerial.'' With respect to final results of administrative reviews, 19 CFR 351.224(e) provides that Commerce ''will analyze any comments received and, if appropriate, correct any ministerial error by amending . . . the final results of review.''

Ministerial Error

Commerce determined that it made an inadvertent error within the meaning of section 751(h) of the Act and 19 CFR 351.224(f) with respect to the treatment of the currency in which Prolamsa incurred its U.S. inventory carrying costs. Accordingly, pursuant to 19 CFR 351.224(e), Commerce is amending the *Final Results* to correct this ministerial error.[4] This correction results in a change to Prolamsa's weighted-average dumping margin. For a complete description and analysis of the specific inadvertent error, and Prolamsa's ministerial error allegation, *see* the accompanying Ministerial Error Allegation Memorandum.[5] The Ministerial Error Allegation 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.*

Rates for Companies Not Selected for Individual Examination

The statute and Commerce's regulations do not address the establishment of a rate to be applied to individual companies not selected for examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the rate for companies which Commerce did not examine in an administrative review. Under section 735(c)(5)(A) of the Act, the all-others rate is normally an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero, *de minimis* (*i.e.,* less than 0.5 percent), or determined entirely on the basis of facts available.

For these amended final results of review, we calculated a weighted-average dumping margin for Prolamsa that is not zero, *de minimis,* or based entirely on the basis of facts available.

The calculated weighted-average dumping margins for the mandatory respondents, Maquilacero S.A. de C.V. (Maquilacero)[6] and Prolamsa, are not zero, *de minimis,* or based entirely on total facts available. Accordingly, Commerce is assigning to the companies not individually examined, listed in the chart below, a margin of 2.86 percent which is the weighted-average of Maquilacero's and Prolamsa's calculated weighted-average dumping margins.[7]

[1] *See Heavy-Walled Rectangular Welded Carbon Steel Pipes and Tubes From Mexico: Final Results of Antidumping Duty Administrative Review; 2021–2022,* 89 FR 24777 (April 9, 2024) (*Final Results*).

[2] *See* Memorandum, ''2021–2022 Antidumping Duty Administrative Review of Certain Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from Mexico,'' dated April 4, 2024.

[3] *See* Prolamsa's Letter, ''Ministerial Error Comments,'' dated April 9, 2024 (Prolamsa's Ministerial Error Allegation).

[4] *See* Memorandum, ''Administrative Review of the Antidumping Duty Order on Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from Mexico; 2021–2022: Ministerial Error Allegation in the Final Results,'' dated concurrently with this notice (Ministerial Error Allegation Memorandum).

[5] *Id.*

[6] We note that the final margin for mandatory respondent, Maquilacero, did not change in these amended final results and continues to be 5.06 percent. *See Final Results,* 89 FR 24778.

[7] *See* Memorandum, ''Calculation of the Weighted-Average Dumping Margin for Non-Selected Companies for the Amended Final Results,'' dated concurrently with this notice. As the weighting factor, we relied on the publicly ranged sales data reported in the quantity and value charts submitted by Maquilacero and Prolamsa.

Amended Final Results

As a result of correcting the ministerial error, Commerce determines that the following estimated weighted-average dumping margins exists for the period September 1, 2021, through August 31, 2022:

Exporter/producer	Weighted-average dumping margin (percent)
Productos Laminados de Monterrey S.A. de C.V	1.61
Review-Specific Average Rate Applicable to the Following Companies	
Aceros del Toro S.A. de C.V	2.86
Aceros El Fraile S.A. de C.V	2.86
Border Assembly S. de R.L. de C.V	2.86
Buffalo Tube S.A. de C.V	2.86
Fortacero S.A. de C.V	2.86
Grupo Collado S.A. de C.V	2.86
Perfiles y Herrajes L.M. S.A. de C.V	2.86
P.J. Trailers Company S.A. de C.V	2.86
Placa y Fierro de Monterrey S.A. de C.V	2.86
Regiomontana de Perfiles y Tubos S.A. de C.V	2.86

Disclosure

Commerce intends to disclose the calculations performed in connection with these amended final results of review to interested parties within five days after public announcement of the amended final results or, if there is no public announcement, within five days of the date of publication of the notice of amended final results in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(1), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess antidumping duties on all appropriate entries of subject merchandise in accordance with this amended final results of this review.

Pursuant to 19 CFR 351.212(b)(1), where Prolamsa reported the entered value of its U.S. sales, Commerce calculated importer-specific *ad valorem* AD assessment rates based on the ratio of the total amount of dumping calculated for each importer's examined sales to the total entered value of those same sales. Where Prolamsa did not report entered value, we calculated a per-unit assessment rate for each importer by dividing the total amount of dumping calculated for the examined sales made to that importer by the total quantity associated with those sales. To determine whether an importer-specific, per-unit assessment rate is *de minimis,* in accordance with 19 CFR 351.106(c)(2), we also calculated an importer-specific *ad valorem* ratio based on estimated entered values. Where Prolamsa's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

For entries of subject merchandise during the POR produced by Prolamsa for which it did not know that its merchandise was destined for the United States, we will instruct CBP to liquidate such entries at the all-others rate established in the less-than-fair-value (LTFV) investigation of 4.91 percent *ad valorem,*[8] if there is no rate for the intermediate company(ies) involved in the transaction.

For the companies identified above that were not selected for individual examination, we will instruct CBP to liquidate entries at the rate equal to the weighted-average dumping margin identified above in the ''Final Results of Review'' section.

Commerce intends to issue assessment instructions to CBP no earlier than 41 days after the date of publication of the final results of this review in the **Federal Register**, in accordance with 19 CFR 356.8(a).

Cash Deposit Requirements

The following amended cash deposit requirements will be effective retroactively upon publication of the amended final results of this administrative review in the **Federal Register**, for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after April 9, 2024, the publication date of the *Final Results,* as provided by section 751(a)(2)(C) of the Act: (1) the amended cash deposit rate for the companies listed above will be equal to the weighted-average dumping margin established in these amended final results of this review; (2) for merchandise exported by companies not covered in this review but covered in a prior completed segment of this proceeding, the cash deposit rate will continue to be the company-specific rate published in the completed segment for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original LTFV investigation, but the producer is, then the cash deposit rate will be the rate established in the completed segment for the most recent period for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 4.91 percent, the all-others rate established in the LTFV investigation.[9] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Administrative Protective Order

This notice also serves as the only reminder to parties subject to an

[8] *See Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Korea, Mexico, and the Republic of Turkey: Antidumping Duty Orders,* 81 FR 62865 (September 13, 2016).

[9] *Id.*

administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(h) and 777(i)(1) of the Act, and 19 CFR 351.224(e).

Dated: May 7, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2024–10846 Filed 5–16–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–044]

1,1,1,2-Tetrafluoroethane (R–134a) From the People's Republic of China: Final Results of the Antidumping Duty Administrative Review; 2022–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that certain companies subject to this administrative review of the antidumping duty order on 1,1,1,2-Tetrafluoroethane (R–134a) from the People's Republic of China (China) remain part of the China-wide entity during the period of review (POR), April 1, 2022, through March 31, 2023.

DATES: Applicable May 17, 2024.

FOR FURTHER INFORMATION CONTACT: John Conniff, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482- 2437.

SUPPLEMENTARY INFORMATION:

Background

On January 25, 2024, Commerce published the preliminary results of this administrative review.[1] No interested party submitted comments concerning the *Preliminary Results* or requested a hearing in this administrative review. Accordingly, the final results remain unchanged from the *Preliminary Results.* Commerce conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The merchandise covered by the order is 1,1,1,2-Tetrafluoroethane, R–134a, or its chemical equivalent, regardless of form, type, or purity level. The chemical formula for 1,1,1,2-Tetrafluoroethane is CF3–CH2 F, and the Chemical Abstracts Service (CAS) registry number is CAS 811–97–2.[2]

Merchandise subject to the order is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheading 2903.45.1000. Although the HTSUS subheading and CAS registry number are provided for convenience and customs purposes, the written description of the scope is dispositive.

Final Results of Review

Because we received no comments, we made no changes from the *Preliminary Results.* We continue to find that certain companies under review did not file a separate rate application and did not demonstrate their eligibility for separate rate status and, therefore, are part of the China-wide entity.[3] As stated in the *Preliminary Results,* no party requested a review of the China-wide entity, and Commerce did not self-initiate a review of the China-wide entity. Because no review of the China-wide entity is being conducted, the China-wide entity's entries were not subject to the review, and the rate applicable to the China-wide entity was not subject to change as a result of this review. Thus, the China-wide entity rate remains 167.02 percent.

Assessment Rates

Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries in accordance with section 751(a)(2)(C) of the Act and 19 CFR 351.212(b). Because we determine that certain companies under review did not demonstrate separate rate eligibility and are part of the China-wide entity, we will instruct CBP to apply an *ad valorem* assessment rate of 167.02 percent to all entries of subject merchandise during the POR that were exported by those companies.[4]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this 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 subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) for previously investigated or reviewed Chinese or 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; (2) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be that for the China-wide entity (*i.e.,* 167.02 percent); and (3) for all non-Chinese exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter that supplied that non-Chinese exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this

[1] *See 1,1,1,2-Tetrafluoroethane (R–134a) from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review and Partial Rescission of Antidumping Duty Administrative Review; 2022–2023, 89 FR 4909 (January 25, 2024) (Preliminary Results).*

[2] 1,1,1,2-Tetrafluoroethane is sold under a number of trade names including Klea 134a and Zephex 134a (Mexichem Fluor); Genetron 134a (Honeywell); Freon™ 134a, Suva 134a, Dymel 134a, and Dymel P134a (Chemours); Solkane 134a (Solvay); and Forane 134a (Arkema). Generically, 1,1,1,2-Tetrafluoroethane has been sold as Fluorocarbon 134a, R–134a, HFC–134a, HF A–134a, Refrigerant 134a, and UN3159.

[3] *See* the appendix to this notice for the list of companies for which a review was requested that are part of the China-wide entity.

[4] *See* the appendix to this notice for the list of companies for which a review was requested that are part of the China-wide entity.

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 Regarding Administrative Protective Order

This notice also serves as a reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing these final results in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.213(h) and 351.221(b)(5).

Dated: May 6, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Companies Under Review That Are Part of the China-Wide Entity

1. Bestcool Inc., Ltd.
2. Electrochemical Factory of Zhejiang Juhua Co., Ltd.
3. Fujian Qingliu Dongying Chemical Ind. Co., Ltd.
4. Hongkong Richmax Ltd.
5. Huantai Dongyue International Trade Co. Ltd.
6. ICOOL Chemical Co., Ltd.
7. Jinhua Binglong Chemical Technology Co., Ltd.
8. Jinhua Yonghe Fluorochemical Co., Ltd.
9. Ningbo FTZ ICOOL Prime International
10. Puremann, Inc.
11. Shandong Dongyue Chemical Co., Ltd.
12. Shandong Huaan New Material Co., Ltd.
13. Sinochem Environmental Protection Chemicals (Taicang) Co., Ltd.
14. Zhejiang Juhua Co., Ltd.
15. Zhejiang Morita New Materials Co., Ltd.
16. Zhejiang Organic Fluor-Chemistry Plant, Zhejiang Juhua Co., Ltd.
17. Zhejiang Quhua Fluor-Chemistry Co., Ltd.
18. Zhejiang Quhua Juxin Fluorochemical Industry Co., Ltd.
19. Zhejiang Quzhou Juxin Fluorine Chemical Co., Ltd.
20. Zhejiang Quzhou Lianzhou Refrigerants Co., Ltd.
21. Zhejiang Yonghe Refrigerant Co., Ltd.
22. Zhejiang Zhonglan Refrigeration Technology Co., Ltd.
23. Zibo Feiyuan Chemical Co., Ltd.

[FR Doc. 2024–10884 Filed 5–16–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD969]

North Pacific Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of hybrid conference meetings.

SUMMARY: The North Pacific Fishery Management Council (Council) and its advisory committees will meet June 3, 2024, through June 12, 2024, in Kodiak, AK.

DATES: The Council's Scientific and Statistical Committee (SSC) will begin at 8 a.m. on Monday, June 3, 2024, and continue through Tuesday, June 4, 2024. The Council's Advisory Panel (AP) will begin at 8 a.m. on Tuesday, June 4, 2024, and again on Friday, June 7, 2024, through Sunday, June 9, 2024. The Council, SSC, and AP will participate in the Climate Scenario Workshop all day on Wednesday, June 5, 2024, and Thursday, June 6, 2024. The Council will begin at 8 a.m. on Friday, June 7, 2024, and continue through Wednesday, June 12, 2024. All times listed are Alaska Time.

ADDRESSES: The meetings will be a hybrid conference. The in-person component of the meeting will be held at the Kodiak Marketplace, 111 W Rezanof Drive, Kodiak, AK 99615, or join the meeting online through the links at *https://www.npfmc.org/upcoming-council-meetings.*

Council address: North Pacific Fishery Management Council, 1007 W 3rd Ave., Suite 400, Anchorage, AK 99501–2252; telephone: (907) 271–2809. Instructions for attending the meeting via webconference are given under Connection Information, below.

FOR FURTHER INFORMATION CONTACT: Diana Evans, Council staff; email: *diana.evans@noaa.gov;* telephone: (907) 271–2809. For technical support, please contact our Council administrative staff, email: *npfmc.admin@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Agenda

Monday, June 3, 2024, Through Tuesday, June 4, 2024

The SSC agenda will include the following issues:

(1) Observer Annual Report for 2023
(2) Bering Sea and Aleutian Island (BSAI) Crab harvest specifications—AIGKC (Aleutian Island Gold King Crab) Stock Assessment and Fishery Evaluation (SAFE) report, acceptable biological catch and overfishing limits (ABC/OFLs), Plan Team report
(3) Small Sablefish Release—initial review
(4) BSAI Crab Program Review—review report (T)

The SSC will also meet in Executive Session on Monday morning, to discuss internal administrative issues. The agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/3047* prior to the meeting, along with meeting materials.

In addition to providing ongoing scientific advice for fishery management decisions, the SSC functions as the Council's primary peer review panel for scientific information, as described by the Magnuson-Stevens Act section 302(g)(1)(e), and the National Standard 2 guidelines (78 FR 43066). The peer-review process is also deemed to satisfy the requirements of the Information Quality Act, including the OMB Peer Review Bulletin guidelines.

Tuesday, June 4, 2024, and Friday, June 7, 2024, Through Sunday, June 9, 2024

The Advisory Panel agenda will include the following issues:

(1) Observer Annual Report for 2023
(2) BSAI Crab harvest specifications—AIGKC SAFE report, ABC/OFLs, Plan Team report
(3) Unobserved Fishing Mortality Workgroup—review report
(4) Small Sablefish Release—initial review
(5) BSAI Crab Program Review—review report
(6) Central Gulf of Alaska (GOA) Rockfish Program Review—review workplan
(7) Research Priorities—adopt 5-year research priorities
(8) BSAI Pot Cod Limited Access Privilege Program (LAPP)—review discussion paper
(9) Staff Tasking

The agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/3046* prior to the meeting, along with meeting materials.

Wednesday, June 5, 2024, Through Thursday, June 6, 2024

The Climate Scenario Workshop agenda will include presentations and discussion on the following topics:

(1) The definition of climate readiness, and opportunities for building climate readiness in the Council process.

(2) Case studies of climate change impacts to Alaska fisheries.

(3) An introduction to the approach of climate scenario planning, and four hypothetical scenarios that will be discussed during breakout sessions.

(4) Breakout discussions to explore the four hypothetical scenarios in depth and generate ideas for approaches the Council could take to build resilience and meet management objectives across a range of possible futures.

(5) Opportunities for ecosystem-based management approaches and information to support climate readiness.

(6) Wrap-up discussions to share highlights from breakout sessions and consider potential next steps.

The agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/3049* prior to the meeting, along with meeting materials.

Friday, June 7, 2024, Through Wednesday, June 12, 2024

The Council agenda will include the following issues. The Council may take appropriate action on any of the issues identified.

(1) B Reports (Executive Director, NMFS Management, NOAA General Counsel (GC), NOAA Enforcement Report, Alaska Fishery Science Center (AFSC), Alaska Department of Fish and Game (ADF&G), United States Coast Guard (USCG), United States Fish and Wildlife Service (USFWS), North Pacific Research Board, Advisory Panel, SSC report)
(2) Observer Annual Report for 2023
(3) BSAI Crab harvest specifications—AIGKC SAFE report, ABC/OFLs, Plan Team report
(4) Unobserved Fishing Mortality Workgroup—review report
(5) Area 4 Vessel Caps—Initial Review
(6) Small Sablefish Release—initial review
(7) BSAI Crab Program Review—review report
(8) Central GOA Rockfish Program Review—review workplan
(9) BSAI Pot Cod LAPP—review discussion paper
(10) Research Priorities—adopt 5-year research priorities
(11) Staff Tasking

The Council will also meet in Executive Session on Friday morning and Saturday afternoon, to discuss internal administrative issues. The agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/3046* prior to the meeting, along with meeting materials.

Connection Information

You can attend the meeting online using a computer, tablet, or smart phone; or by phone only. Connection information will be posted online at: *https://www.npfmc.org/upcoming-council-meetings.* For technical support, please contact our administrative staff, email: *npfmc.admin@noaa.gov.*

If you are attending the meeting in-person, please refer to the COVID avoidance protocols on our website, *https://www.npfmc.org/upcoming-council-meetings/.*

Public Comment

Public comment letters will be accepted and should be submitted electronically through the links at *https://www.npfmc.org/upcoming-council-meetings.* The Council strongly encourages written public comment for this meeting, to avoid any potential for technical difficulties to compromise oral testimony. The written comment period is open from May 10, 2024, to May 31, 2024, and closes at 12 p.m. Alaska time on Friday, May 31, 2024.

Although other non-emergency issues not on the agenda may come before these groups for discussion, those issues may not be the subject of formal action during these meetings. Actions 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 Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: May 14, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–10854 Filed 5–16–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD965]

Magnuson-Stevens Fishery Conservation and Management Act Provisions; 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: The Assistant Regional Administrator for Sustainable Fisheries, Greater Atlantic Region, NMFS, has made a preliminary determination that an Exempted Fishing Permit (EFP) application contains all of the required information and warrants further consideration. The EFP would allow federally permitted commercial fishing vessels to fish outside fishery regulations in support of exempted fishing activities proposed by the NOAA Northeast Fisheries Science Center (NEFSC). 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 EFPs.

DATES: Comments must be received on or before June 3, 2024.

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.''

All comments received are a part of the public record and may be posted for public viewing 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 ''anonymous'' as the signature if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Christine Ford, Fishery Management Specialist, *Christine.Ford@noaa.gov,* (978) 281–9185.

SUPPLEMENTARY INFORMATION: The NOAA NEFSC submitted a complete application for an EFP to conduct

commercial fishing activities that the regulations would otherwise restrict, to continue trials of on-demand fishing gear that use one or no surface buoys and to test the ability of gear marking systems to consistently locate gear. This EFP would exempt the participating vessels from the following Federal regulations:

TABLE 1—REQUESTED EXEMPTIONS

CFR citation	Regulation	Need for exemption
50 CFR 697.21(b)	Gear marking requirements	For trial of trap/pot gear with no more than one surface marking on trawls of more than three traps, and trial of trap/pot gear with no surface marking on trawls of three or fewer traps.
50 CFR 648.84(b)	Gear marking requirements	For trial of gillnet gear with no more than one surface marking.
50 CFR 648.264(a)	Gear marking requirements	For trial of red crab trap/pot gear with no more than one surface marking on trawls.

TABLE 2—PROJECT SUMMARY

Project title	Development and trials of on-demand fishing systems in fixed gear fisheries.
Project start	08/22/2024.
Project end	12/31/2025.
Project objectives	To expand the trials of on-demand fishing systems with additional participants and fisheries to ensure testing has been conducted adequately across the breadth of regional commercial fishing conditions, with the aim of sustaining the fixed gear fishing industry, while reducing the entanglement risk to the critically endangered North Atlantic Right Whale.
Project location	Areas open to trap/pot and gillnet fishing in the Gulf of Maine, Georges Bank, southern New England, and mid-Atlantic.
Number of vessels	*Lobster:* up to 180, including up to 5 using grappling; *Gillnet & other trap/pot:* up to 20.
Number of trips	Up to 15,000 trips (200 vessels making an average of 1.5 trips per week) for trap/pot vessels; Up to 1,600 trips (20 vessels making an average of 1.5 trips per week) for gillnet vessels.
Trip duration (days)	*Lobster:* Ranging from 1–14 days depending on the fishing area. *Gillnet & other trap/pot:* Variable based on fishery, target species, and fishing location, but within the range of standard commercial fishing trips.
Gear type(s)	Trap/pot and anchored-fixed gillnet.
Number of tows or sets	*Lobster:* Overall lobster fleet research effort will be capped at 1,800 modified trap trawls actively fished. The number of on-demand units actively fished per vessel will vary by season and fishing operation. *Gillnet & other trap/pot:* Combined research effort for these fisheries will be capped at 200 on-demand units actively fishing.
Duration of tows or sets	*Lobster:* Variable, but expected to be 14 days or less. Will not exceed 30 days, as required by regulation. *Gillnet & other trap/pot:* Typical commercial soak times.

Project Narrative

This project is a continuation and broadening of the NEFSC's efforts to trial on-demand fishing systems (also known as ropeless) aimed at reducing the entanglement risk to protected species, mainly the North Atlantic right whale, in trap/pot and gillnet fisheries. The NEFSC's existing EFP will expire on August 21, 2024, and authorizes on-demand gear trials on up to 195 trap/pot vessels and up to 5 gillnet vessels. As of March 2024, the NEFSC had collected data from 1,268 hauls of on-demand gear in Federal waters under its current EFP. Of these, 587 hauls took place in Lobster Management Area (LMA) 1, 199 in LMA 2, 437 in LMA 3, 19 in LMA Outer Cape, and 26 in the gillnet fishery. Between August 2023 and March 2024, the NEFSC reported four instances of gear loss not associated with gear conflict, and three assumed instances of gear conflict. For the assumed gear conflict instances, two likely involved groundfish trawlers, while the other may have involved discarded tilefish gear. The NEFSC has continued to conduct outreach to encourage use of the Trap Tracker app by non-participating vessels. As of March 2024, approximately 44 fixed-gear and 6 mobile-gear vessels are using Trap Tracker.

This project would allow up to 180 lobster trap vessels to replace up to 10 of their existing trawls (up to 1,800 trawls total) with modified trawls, including in Atlantic Large Whale Take Reduction Plan (ALWTRP) Restricted Areas. It would also allow up to 20 total gillnet, red crab trap, and black sea bass pot vessels to replace up to 10 of their existing strings/trawls (up to 200 strings/trawls) with modified strings/trawls; these gear types would not be allowed in the ALWTRP Restricted Areas. Modified gear would replace one or both traditional end lines with acoustic on-demand systems and other alternatives to static buoy lines (including, but not limited to, spooled systems, buoy and stowed-rope systems, lift-bag systems, and grappling).

The ultimate goal of this project is to enable the continuation of some of the region's most valuable and historically significant fisheries while also meeting the requirements set forth by the ALWTRP and section 118(f) of the Marine Mammal Protection Act, specifically reducing the level of serious injury and mortality of North Atlantic right, humpback, and fin whales in commercial fisheries. To achieve this, the project includes objectives to test the efficacy of fully on-demand trawls/strings and the adequacy of gear marking systems that use data hubs and visualization platforms to share on-demand gear locations. The project is intended to address challenges and data needs associated with on-demand gear, including:

- Collecting data on location accuracy and gear conflict concerns, comparative timing of on-demand vs. traditional fishing modalities, refining hauling failures, and gathering industry feedback about usability and safety;
- Conducting data analysis on gear durability, manufacturer-specific performance reports and recommendations, and initiation of a list of criteria that could be used to

certify or type approve innovative gear technologies;

- Continuing to evaluate the reliability of new innovative gears as they come on the market and work with manufacturers and industry to pilot test gears;
- Expanding experimental fishing in Restricted Areas in ways that make sense, focusing on safety (protected species and fishermen) and equity (fishermen and manufacturers) to assess the feasibility and efficiency of fishing fully on-demand trawls/strings; and
- Expanding communication efforts to participants, the broader fishing community, managers, and partners.

To ensure that on-demand fishing and gear marking technologies are adequately tested across the breadth of regional commercial fishing conditions, the NEFSC requests the flexibility to test on-demand gear across the geographic range of the Federal American lobster and Jonah crab fishery, including testing fully on-demand gear (no persistent vertical lines) in ALWTRP Restricted Areas. It also requests the opportunity to trial on-demand gillnet and other trap/pot gear across the Gulf of Maine, Georges Bank, southern New England, and the mid-Atlantic. In recognition of industry's interest in grappling as a low-cost alternative to acoustic on-demand systems, this project would also allow up to 5 vessels to retrieve up to 30 trawls via grappling. Although no grappling trials have occurred to date, four vessels/operators have expressed interest in participating in the study. Unlike what is authorized under the existing EFP, no grappling would be allowed in the ALWTRP Restricted Areas. To cover a greater area and target areas where data is needed, NEFSC has requested the flexibility to have greater than 200 participants during the permit period (with only 200 fishing at one time). It would provide requested modifications to the active participants, general locations, and technologies to be tested 1 month in advance. Priority would be given to participants who are seasonally excluded from fishing in certain areas and/or in offshore fisheries with limited entanglement mitigation options.

This permit would only exempt vessels from the specified Federal regulations in Federal waters. It would not exempt the vessels from any requirements imposed by any State, the Endangered Species Act, the Marine Mammal Protection Act, or any other applicable laws. The applicant would be responsible for obtaining all required State authorizations. Other than gear markings, all trap/pot trawls and gillnet strings would be consistent with the regulations of the management area where the vessel is fishing and would be fished in accordance with the participating vessels' standard operations (number and length of trips, soak times, trap limits, *etc.*).

The use of on-demand lobster trap gear in the ALWTRP Restricted Areas is limited to gear without any persistent vertical lines. The NEFSC's existing EFP allows vessels to modify up to 20 trawls each, but caps effort to 300 total trawls in the Restricted Areas. If necessary due to a high level of interest and limited capacity, the NEFSC may require a demonstrated history of fishing within ALWTRP Restricted Areas as a condition for participation in on-demand trials in those areas.

In the first phase of participation, staff from the NEFSC and the gear manufacturers would provide training to ensure the system is working as intended and all participants have sufficient experience with the gear before borrowing from the gear cache library. In the second phase, participating vessels would rig an on-demand system to one end of a standard trawl or string and fish it as a hybrid (with 1 traditional surface marking) for at least 10 hauls per system. In phase three, participants would fish the gear as part of normal fishing operations, including fishing fully on-demand gear and fully on-demand trap trawls in the ALTWRP Restricted Areas. In some cases, a scientific observer may be on board, and/or GoPro Systems (or equivalent) may record gear retrievals. The NEFSC would provide standardized data collection sheets to all participants, but individually-identifiable data will only be made public with the express permission of the vessel owner.

The NEFSC also plans to include targeted geolocation studies in areas with limited trawling and/or dredging to test new location-marking systems on the seafloor and automated location-marking when gear is set and retrieved. This EFP would support efforts to improve gear-marking and gear-conflict avoidance technologies, including testing the amount of effort to mark sub-surface gear location in the Trap Tracker app (vs. surface location where the gear is deployed) and other sub-surface gear marking technologies. This EFP would also test the use of the EarthRanger platform that displays gear locations from various gear-marking technologies. The NEFSC would demonstrate and encourage adoption of these technologies with non-participant vessels.

The NEFSC proposes the following best practices and risk reduction measures:

- All vessels would report all right whale sightings to NMFS via *ne.rw.survey@noaa.gov* or NOAA (866–755–6622) or the U.S. Coast Guard (Channel 16) and record sightings on data sheets;
- All vessels would retrieve on-demand vertical lines as quickly as possible to minimize time in the water column;
- All vessels would adhere to current approach regulations—a 500-yard (457.2-meter) buffer zone created by a surfacing right whale—and must depart immediately at a safe and slow speed, in accordance with current regulations. Hauling any lobster gear would immediately cease (by removal) to accommodate the regulation and be reinitiated only after it is reasonable to assume the whale has left the area;
- All vessels would provide mandatory, weekly gear loss reports;
- All vessels would operate within a 10-knot speed limit when transiting Restricted Areas or when whales are observed;
- For fully on-demand gear without traditional surface markings, participants would use the Trap Tracker or an equivalent technology for retrieval and set positioning details, which would be available to Federal, State, and corresponding enforcement personnel, as well as other fishermen;
- For fully on-demand gear without traditional surface markings, on-demand vertical lines would be marked with unique yellow/black/orange marks above the regional markings, in addition to ALWTRP regulations (per agreement with the NMFS Atlantic Large Whale Take Reduction Team Coordinator);
- When fishing in ALWTRP Restricted Areas, vessels would check real-time right whale sightings information (such as Right Whale Sightings Advisories and Whale ALERT) before setting any gear and avoid areas of high right whale abundance, and all vessels would be recommended to follow this process when setting gear outside the ALWTRP Restricted Areas;
- Enforcement will be provided with and trained on the Trap Tracker app (for seeing subsea marked gear) prior to the start of the trials;
- A unique flag will be flown by each vessel for enforcement recognition; and
- The NEFSC would continue to provide regular updates to the Greater Atlantic Regional Fisheries Office (GARFO), the New England and Mid-Atlantic Fishery Management Councils, the Atlantic States Marine Fisheries Commission, and constituents on project developments and performance.

Vessels fishing fully on-demand lobster trawls in ALWTRP Restricted

Areas would be required to follow additional practices:

- All participants would carry a NEFSC scientist on a subset of trips to collect additional data and oversee trial performance;
- Stowed hauling lines in on-demand units would contain unique colored identification marks consisting of orange marks above each regional ALWTRP marking;
- No floating groundline would be used on research trawls, including where otherwise legally allowed between the first trap and anchor or on-demand unit;
- If any large whale species came within 500 yards (457.2 meters) of a participating vessel during hauling, fishing would immediately cease, by either removal or resetting, and be reinitiated only after it was reasonable to assume the whale(s) had left the area; and
- Participants will be provided with information on species identification as well as protocols to report live, dead, or entangled sightings of all large whale species. All whale sightings would be recorded on data sheets.

If approved, the applicant may request minor modifications and extensions to the EFP throughout the year. EFP modifications and extensions may be granted without further notice if they are deemed essential to facilitate completion of the proposed research and have minimal impacts that do not change the scope or impact of the initially approved EFP request. Any fishing activity conducted outside the scope of the exempted fishing activity would be prohibited.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: May 13, 2024.

Kelly Denit,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–10850 Filed 5–16–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD968]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council) will hold public meetings of the Council and Executive Committee, including a joint session with the Atlantic States Marine Fisheries Commission (ASMFC) Summer Flounder, Scup, and Black Sea Bass Management Board.

DATES: The meetings will be held Tuesday, June 4 through Thursday, June 6, 2024. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: This meeting will be an in-person meeting with a virtual option. Council members, other meeting participants, and members of the public will have the option to participate in person at Atlantis Banquets and Events, 431 E Main Street Riverhead, NY 11901, or virtually via Webex webinar. Webinar connection instructions and briefing materials will be available at: *https://www.mafmc.org/briefing/june-2024.*

Council address: Mid-Atlantic Fishery Management Council, 800 N State St., Suite 201, Dover, DE 19901; telephone: (302) 674–2331; *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D. Executive Director, Mid-Atlantic Fishery Management Council; telephone: (302) 526–5255. The Council's website, *www.mafmc.org,* also has details on the meeting location, proposed agenda, webinar listen-in access, and briefing materials.

SUPPLEMENTARY INFORMATION: The following items are on the agenda, although agenda items may be addressed out of order (changes will be noted on the Council's website when possible.)

Tuesday, June 4, 2024

Executive Committee—Closed Session

Recommend Advisory Panel appointments

——— LUNCH ———

Executive Committee—Open Session

2025–2029 Strategic Plan: Discuss Vision, Mission, and Goals

Summer Flounder Mesh Exemptions Framework/Addendum (Joint With ASMFC Summer Flounder, Scup, Black Sea Bass Board)

Consider addition of alternatives to revise Small Mesh Exemption Program review trigger

Review additional analysis and revised action plan

Wednesday, June 5, 2024

Atlantic Surfclam and Ocean Quahog Species Separation Requirements Amendment

Review summary from hearing/public comment period

Select Council preferred alternative and take final action

——— LUNCH ———

2025 Chub Mackerel Specifications

Review recommendations from the Advisory Panel, SSC, Monitoring Committee, and staff

Review previously adopted 2025 specifications and management measures, and recommend changes if necessary

2025 Longfin Squid Specifications

Review recommendations from the Advisory Panel, SSC, Monitoring Committee, and staff

Review previously adopted 2025 specifications and management measures, and recommend changes if necessary

2025 Illex Squid Specifications

Review recommendations from the Advisory Panel, SSC, Monitoring Committee, and staff

Review previously adopted 2025 specifications and management measures, and recommend changes if necessary

Unmanaged Commercial Landings Report

Review EOP Advisory Panel and Committee input

Review report and provide feedback

SSC's Overfishing Limit (OFL) Coefficient of Variation (CV) Guidance Document

Review and approve updates

Acknowledgment of Outgoing Council Members

Thursday, June 6, 2024

Business Session

Committee Reports (SSC); Executive Director's Report; Organization Reports; and Liaison Reports

Other Business and General Public Comment

Although non-emergency issues not contained in this agenda may come before this group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during these meetings. Actions 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 Council's intent to take final action to address the emergency.

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.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: May 14, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–10853 Filed 5–16–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Alaska Mariculture Economic Benchmark Survey

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on February 21, 2024 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic and Atmospheric Administration, Commerce

Title: Alaska Mariculture Economic Benchmark Survey

OMB Control Number: 0648–XXXX.

Form Number(s): None.

Type of Request: Regular submission [new information collection].

Number of Respondents: 80.

Average Hours per Response: 30 minutes.

Total Annual Burden Hours: 60 hours.

Needs and Uses: This is a request for a new collection of information. Alaska was recently named an Aquaculture Opportunity Area (AOA) under NOAA Fisheries to determine geographic areas that are environmentally, socially, and economically suitable to support commercial aquaculture operations. The purpose of this data collection is to gather economic data from current growers that hold an Aquatic Farming permit under the Alaska Department of Fish & Game to establish a benchmark economic report that presents economic measures (profitability, breakeven price, etc.) and operations (average stocking density, kelp line depth and separation, etc.) spatially.

The data collected from this survey will be used by NOAA economists to generate a benchmark report that states spatial economic information, internal reports on the spatial economic suitability of an Alaskan mariculture operation, and external publications on the financial and environmental risks. These reports will be published on NOAA's website and be publicly accessible for stakeholders, researchers, and other members of the public.

Stakeholders (current and prospective growers) are requesting economic information to help secure small business loans to establish new growing operations and expand current production and describe the economics of opening and operating a mariculture farm in Alaska. Additionally, the economic data provided from this collection will help determine the spatial economic suitability requested from the AOA project. NOAA will use the information provided in the survey to generate a bio economic model that can be simulated under various financial and environmental scenarios. Examples of financial and environmental scenarios include the impact to profitability from subsidies for reductions in seed costs, price floors, and reduced transportation costs from a new production facility and impact to growth and mortality rates from increasing surface water temperatures, dissolved oxygen (DO), and other water parameters and other environmental events such as harmful algae blooms (HAB) or severe storms.

Affected Public: Business or other for-profit organizations; Not-for-profit institutions; Farms.

Frequency: Annually.

Respondent's Obligation: Voluntary.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering the title of the collection.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2024–10908 Filed 5–16–24; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Deletions from the Procurement List.

SUMMARY: This action deletes product(s) from the Procurement List that were be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Date added to and deleted from the Procurement List:* June 16, 2024.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Suite 325, Washington, DC 20064.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, telephone: (703) 489–1322, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Deletions

On 4/12/2024 (89 FR 25865), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List. This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3.

After consideration of the relevant matter presented, the Committee has determined that the product(s) listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or

other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the product(s) to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the product(s) deleted from the Procurement List.

End of Certification

Accordingly, the following product(s) are deleted from the Procurement List:

Product(s)

NSN(s)—Product Name(s):
7530–01–517–2729—Folder, File, Pressboard, Expanding, Two 1½″ Fasteners, Green, Letter
7530–01–517–2730—Folder, File, Pressboard, Expanding, One 1½″ Fastener, Green, Letter
7530–01–484–1865—Folder, File, Pressboard, Expanding, One 1½″ Fastener, Green, Legal
Authorized Source of Supply: LC Industries, Inc., Durham, NC
Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR(2, NEW YORK, NY

NSN(s)—Product Name(s):
8520–01–555–2891—Cleaner, Hand, Biorenewable, Waterless, Pumice, 1 gl
8520–01–555–2902—Cleaner, Hand, Biorenewable, Waterless, 1 gl
Authorized Source of Supply: Outlook Nebraska, Inc, Omaha, NE
Contracting Activity: GSA/FSS GREATER SOUTHWEST ACQUISITI, FORT WORTH, TX

NSN(s)—Product Name(s):
8520–01–555–2891—Cleaner, Hand, Biorenewable, Waterless, Pumice, 1 gl
8520–01–555–2902—Cleaner, Hand, Biorenewable, Waterless, 1 gl
Authorized Source of Supply: VisionCorps, Lancaster, PA
Contracting Activity: GSA/FSS GREATER SOUTHWEST ACQUISITI, FORT WORTH, TX

NSN(s)—Product Name(s):
7530–00–NIB–0675—Classification Folder, Pressboard, 4 Part, 1 Divider, Legal Size, Dark Green
7530–00–NIB–0676—Classification Folder, Pressboard, 4 Part, 1 Divider, Legal Size, Yellow
7530–00–286–7287—Folder, File, Pressboard, ⅕ Cut Tab, Light Green, Legal
7530–00–926–8984—Folder, File, Pressboard, End or Side Self Tab, 1″ Fastener, Light Green, Legal
7530–00–985–7009—Folder, File, Pressboard, 1″ Capacity, Straight Cut Tab, Red, Letter
Authorized Source of Supply: Georgia Industries for the Blind, Bainbridge, GA
Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR(2, NEW YORK, NY

NSN(s)—Product Name(s):
2815–01–464–5543—Parts Kit, Piston Assembly, HMMWV Engine
Authorized Source of Supply: Georgia Industries for the Blind, Bainbridge, GA
Contracting Activity: DLA LAND AND MARITIME, COLUMBUS, OH

Michael R. Jurkowski,

Director, Business Operations.

[FR Doc. 2024–10894 Filed 5–16–24; 8:45 am]

BILLING CODE 6353–01–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Generic Clearance for the Collection of Test and Pilot Data

AGENCY: Corporation for National and Community Service.

ACTION: Notice of information collection; request for comment.

SUMMARY: The Corporation for National and Community Service, operating as AmeriCorps, has submitted a public information collection request (ICR) entitled Generic Clearance for the Collection of Pilot and Test Data for review and approval in accordance with the Paperwork Reduction Act.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by June 17, 2024.

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: Copies of this ICR, with applicable supporting documentation, may be obtained by calling Amy Borgstrom at 202–422–2781 or by email to *aborgstrom@americorps.gov.*

SUPPLEMENTARY INFORMATION: The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of AmeriCorps, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions;
- Propose ways to enhance the quality, utility, and clarity of the information to be collected; and
- Propose ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments

A 60-day Notice requesting public comment was published in the **Federal Register** on February, 28, 2024 at 89 FR 14638. This comment period ended April 28, 2024. No comments were received.

Title of Collection: Generic Clearance for the Collection of Pilot and Test Data.

OMB Control Number: 3045–0163.

Type of Review: Renewal.

Respondents/Affected Public: Individuals and Households.

Total Estimated Number of Annual Responses: 700.

Total Estimated Number of Annual Burden Hours: 350.

Abstract: AmeriCorps seeks to renew the current information collection. The information collection will enable pilot testing of survey instruments in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By pilot testing we mean information that provides useful insights on how respondents interact with the instrument but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations regarding prospective studies. It will also allow feedback to contribute directly to the improvement of research program management.

The Agency will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;

• Personally identifiable information (PII) is collected only to the extent necessary and is not retained;

• Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency;

• Information gathered will not be used for the purpose of substantially informing influential policy decisions; and

• Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address the target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

As a general matter, information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. The information collection will be used in the same manner as the existing application. AmeriCorps also seeks to continue using the current application until the revised application is approved by OMB. The current application expired on April 30, 2024.

Mary Hyde,

Director, Office of Research and Evaluation.

[FR Doc. 2024–10866 Filed 5–16–24; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Office of the Department of the Air Force

Department of the Air Force Scientific Advisory Board; Notice of Federal Advisory Committee Meeting

AGENCY: Department of the Air Force Scientific Advisory Board, Department of the Air Force.

ACTION: Notice of Federal advisory committee meeting.

SUMMARY: The Department of Defense (DoD) is publishing this notice in accordance with chapter 10 of title 5, United States Code, to announce that the following meeting of the Department of the Air Force Scientific Advisory Board will take place.

DATES: Closed to the public. 25 June 2024 from 8:00AM–4:00p.m. Pacific Time and 26 June 2024 from 8:00a.m.–4:00p.m. Pacific Time.

ADDRESSES: The meeting will be held at the Aerospace Corporation Campus, 2310 E. El Segundo Blvd., El Segundo, CA 90245–4609.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Scales, (202) 528–7266 (Voice), *michael.scales.6@us.af.mil* (Email). Mailing address is 1500 West Perimeter Road, Ste. #3300, Joint Base Andrews, MD 20762. Website: *https://www.scientificadvisoryboard.af.mil/.* The most up-to-date changes to the meeting agenda can be found on the website.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of chapter 10 of title 5, United States Code (as enacted on Dec. 27, 2022, by section 3(a) of Public Law 117–286) (formerly the Federal Advisory Committee Act, 5 U.S.C., Appendix), section 552b of title 5, United States Code (popularly known as the Government in the Sunshine Act), and 41 CFR 102–3.140 and 102–3.150. Purpose of the Meeting: The purpose of this Department of the Air Force Scientific Advisory Board meeting is to provide dedicated time for members to engage with warfighter and defense industry partners and finalize and vote on the FY24 Air Force Research Laboratory Science & Technology Review's Integrated Outbrief.

Agenda: [All times are Pacific Time]

Tuesday, 25 June 2024:

0800–0820 Registration
0820–0830 Facility Logistics
0830–0900 Welcome Briefing
0900–0945 FY24 SAB Summer Board Welcome
0945–1000 AQB Update
1015–1115 FY24 S&T Review Outbrief & Vote #1
1115–1215 FY24 S&T Review Outbrief & Vote #2
1315–1415 FY24 S&T Review Outbrief & Vote #3
1415–1500 SAF/OS Brief
1500–1600 SSC Threat Brief

Wednesday, 26 June 2024:

0800–0900 USSF(S4S) Capability/Threat Brief
0900–0945 Tech Brief #1
1000–1045 Tech Brief #2
1045–1130 Tech Brief #3
1230–1315 Tech Brief #4
1315–1400 Tech Brief #5
1415–1500 Tech Brief #6
1500–1600 NRO Brief

In accordance with section 1009(d) of title 5, United States Code (formerly sec. 10(d) of the Federal Advisory Committee Act, 5 U.S.C. Appendix) and 41 CFR 102–3.155, the Administrative Assistant of the Air Force, in consultation with the Air Force General Counsel, has agreed that the public interest requires this meeting of the United States Department of the Air Force Scientific Advisory Board be closed to the public because it will involve discussions involving classified matters covered by section 552b(c)(1) of title 5, United States Code.

Written Statements: Any member of the public wishing to provide input to the United States Department of the Air Force Scientific Advisory Board should submit a written statement in accordance with 41 CFR 102–3.140(c), section 1009(a)(3) of title 5, United States Code (formerly sec. 10(a)(3) of the Federal Advisory Committee Act), and the procedures described in this paragraph. Written statements can be submitted to the Designated Federal Officer at the address detailed above at any time. The Designated Federal Officer will review all submissions with the Department of the Air Force Scientific Advisory Board Chairperson and ensure they are provided to members of the Department of the Air Force Scientific Advisory Board. Written statements received after the meeting that is the subject of this notice may not be considered by the Scientific Advisory Board until the next scheduled meeting.

Tommy W. Lee,

Acting Air Force Federal Register Liaison Officer.

[FR Doc. 2024–10883 Filed 5–16–24; 8:45 am]

BILLING CODE 3911–44–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2024–HQ–0007]

Proposed Collection; Comment Request

AGENCY: Department of the Army, Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Director of Army Safety announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by July 16, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Office of the Director of Army Safety (ODASAF), 2530 Crystal Dr., Arlington, VA 22202, ATTN: Mr. Tim Mikulski, or call ODASAF at (703) 697–1321.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Radiation Exposure Data Collection; DD Form 1952 (Dosimetry Application and Record of Previous Radiation Exposure), DA Form 7689 (Bioassay Information Summary Sheet); OMB Control Number 0702–0150.

Needs and Uses: The information collection requirement is to document and record an individual's external and internal short and long-term exposure to radioactive materials and radiation generating equipment. The information collection is also utilized to monitor, evaluate, and control the risks and associated health hazards, conduct investigations, management studies and training to ensure individual qualifications and education in handling radioactive materials are maintained in compliance with the Nuclear Regulatory Commission (NRC) 10 CFR part 20, Army NRC license conditions, and Occupational Safety and Health Administration (OSHA) 29 CFR 1926.53.

Affected Public: Individuals or households.

Annual Burden Hours: 12.5.

Number of Respondents: 50.

Responses per Respondent: 1.

Annual Responses: 50.

Average Burden per Response: 15 minutes.

Frequency: On occasion.

Dated: May 13, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–10913 Filed 5–16–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2024–OS–0052]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Acquisition and Sustainment (OUSD(A&S)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the OUSD(A&S) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by July 16, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to OUSD(A&S), 1400 Defense Pentagon, Washington, DC 20301, ATTN: Dr. Maureen Raley, or call 571–372–6278.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Trusted Capital Digital Marketplace Application; OMB Control Number 0704–0596.

Needs and Uses: Per the authority vested in the Secretary of Defense (SECDEF) by Section 1711 of the National Defense Authorization Act of 2018, the OUSD(A&S) proposed a ''Trusted Capital'' initiative in the form of a public-private partnership designed to convene trusted sources of private capital with innovative companies critical to the defense industrial base (DIB) and national security. The initiative included the establishment of a Trusted Capital Digital Marketplace (TCDM) to facilitate business relationships between eligible investors

(''Capital Providers'') and eligible small and medium-sized businesses that have been ''down-selected'' by Department of Defense (DoD) Components based on relevancy, technical merit, business viability, or innovativeness (''Capability Providers''). The COVID–19 pandemic highlighted the criticality of the security and resiliency of defense supply chains. The Federal emergency enabled DoD to accelerate initiatives to identify constraints and risks in our supply chains that were initially identified in the Executive Order (E.O.) 13806 report, which was published in 2018. One of the risk archetypes identified in the report is foreign dependency on capital and supply chains. The OUSD(A&S) Trusted Capital program offers critical technology companies an alternative to adversarial capital. To accomplish this important national security mission the Trusted Capital program must gather data required to conduct national security and supply chain due-diligence to prioritize ''trusted'' sources of commercial capital. Information collected will be used in determining an applicant's eligibility for TCDM participation. Parties complete an electronic application and are subjected to a due diligence screening process to assess for adversarial foreign ownership, influence, or control—as well as other national security risks. In the event additional information is necessary to process an application, additional inquiries may be sent to the applicant. Applicants that receive a favorable due diligence screening adjudication by OUSD(A&S) are approved for TCDM participation. In addition to initial application requirements, participants will be subject to continuous reporting obligations.

Affected Public: Business or other for-profit.

Annual Burden Hours: 450.

Number of Respondents: 300.

Responses per Respondent: 1.

Annual Responses: 300.

Average Burden per Response: 90 minutes.

Frequency: On occasion.

Dated: May 13, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–10912 Filed 5–16–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2024–HA–0051]

Proposed Collection; Comment Request

AGENCY: The Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Health Agency announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by July 16, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Defense Health Agency, 7700 Arlington Blvd., Falls Church, VA 22042, ATTN: Amanda Grifka, 703–681–1771.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: COVID–19 Vaccine Screening and Immunization Documentation; DHA Form 207; OMB Control Number 0720–0068.

Needs and Uses: The Defense Health Agency (DHA) created the DHA Form 207, ''COVID–19 Vaccine Screening and Immunization Documentation,'' to determine if the COVID–19 vaccine can be administered to a patient. The DHA Form 207 is used to determine and document patient eligibility and vaccine declinations for a COVID–19 vaccination. Respondents include Active Duty military members, Federal employees, beneficiaries, and contractors (based on their employment) who wish to receive the vaccine. On 2 November 2021, the Centers for Disease Control Advisory Committee on Immunization Practices approved the clinical recommendations for the use of select COVID–19 vaccines for pediatrics ages 5–11 years. The DHA Form 236 is used to determine pediatric patient clinical eligibility for receipt of a COVID–19 vaccination. Respondents are DoD beneficiaries parents or guardians of children receiving a vaccination. The process for completing this form is the identical to the DHA Form 207.

Affected Public: Individuals or households.

Annual Burden Hours: 2,600.

Number of Respondents: 78,000.

Responses per Respondent: 1.

Annual Responses: 78,000

Average Burden per Response: 2 minutes.

Frequency: As needed, during COVID season Aug–May seasonally.

Dated: May 13, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–10915 Filed 5–16–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2024–OS–0053]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense (Comptroller)/Chief Financial Officer, Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Finance and Accounting Service announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by July 16, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Defense Finance and Accounting Services, 8899 E 56th St, Indianapolis, IN 46249, ATTN: Ms. Kellen Stout, or call 317–212–1801.

SUPPLEMENTARY INFORMATION: *Title; Associated Form; and OMB Number:* Claim Certification and Voucher for Death Gratuity Payment; DD Form 397; OMB Control Number 0730–0017.

Needs and Uses: The information collection requirement allows the government to collect the signatures and information needed to pay a death gratuity. Pursuant to 10 U.S.C. 1475–1480, a designated beneficiary or next-of-kin can receive a death gratuity payment for a deceased service member. This form serves as a record of the disbursement. The DoD Financial Management Regulation (FMR), Volume 7A, Chapter 36, defines the eligible beneficiaries and procedures for payment. To provide internal controls for this benefit, and to comply with the above-cited statutes, the information requested is needed to substantiate the receipt of the benefit.

Affected Public: Individuals or households.

Annual Burden Hours: 250.

Number of Respondents: 500.

Responses per Respondent: 1.

Annual Responses: 500.

Average Burden per Response: 30 minutes.

Frequency: On occasion.

Dated: May 13, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–10916 Filed 5–16–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID: USN–2024–HQ–0007]

Proposed Collection; Comment Request

AGENCY: Department of the Navy, Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Department of the Navy announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by July 16, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Millennium Cohort Program, 140 Sylvester Road, San Diego, CA 92106, Dr. Rudolph Rull, (888) 942–5222, *usn.nhrc-MilcohortInfo@health.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Prospective Studies of US Military Forces and Their Families: The Millennium Cohort Program; OMB Control Number 0703–0064.

Needs and Uses: The information collection requirement is necessary to respond to recommendations by Congress and by the Institute of Medicine to perform investigations that systematically collect population-based demographic and health data so as to track and evaluate the health of military personnel throughout the course of their careers and after leaving military service. The Millennium Cohort Family Study also evaluates the impact of military life on military families. The study team will also deploy on-line market research surveys to study participants to better understand their preferences and motivations and inform outreach strategies.

Affected Public: Individuals or households.

Millennium Cohort Study Follow-Up Survey

Annual Burden Hours: 132,845.

Number of Respondents: 177,127.

Responses per Respondent: 1.

Annual Responses: 177,127.

Average Burden per Response: 45 minutes.

Millennium Cohort Study Participant Feedback Survey

Annual Burden Hours: 23,027.
Number of Respondents: 177,127.
Responses per Respondent: 1.
Annual Responses: 177,127.
Average Burden per Response: 7.8 minutes.

Millennium Cohort Family Study Follow-Up Survey

Annual Burden Hours: 14,084.
Number of Respondents: 16,901.
Responses per Respondent: 1.
Annual Responses: 16,901.
Average Burden per Response: 50 minutes.

Total

Annual Burden Hours: 169,956.
Number of Respondents: 194,028 (respondents to non-Family follow-up and participant feedback surveys are the same).
Annual Responses: 371,155.
Frequency: On occasion.

Dated: May 13, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–10914 Filed 5–16–24; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

[[Docket No.: ED–2024–SCC–0045]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; College Affordability and Transparency Explanation Form (CATEF)

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing an extension without change of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before June 17, 2024.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link *www.reginfo.gov/public/do/PRAMain* to access the site. Find this information collection request (ICR) by selecting ''Department of Education'' under ''Currently Under Review,'' then check the ''Only Show ICR for Public Comment'' checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the ''View Information Collection (IC) List'' link. Supporting statements and other supporting documentation may be found by clicking on the ''View Supporting Statement and Other Documents'' link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Amy Wilson, 202–987–1318.

SUPPLEMENTARY INFORMATION: The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: College Affordability and Transparency Explanation Form (CATEF).

OMB Control Number: 1840–0822.

Type of Review: An extension without change of a currently approved ICR.

Respondents/Affected Public: Private Sector.

Total Estimated Number of Annual Responses: 487.

Total Estimated Number of Annual Burden Hours: 1,193.

Abstract: The Office of Postsecondary Education (OPE) is seeking a renewed three-year clearance for the College Affordability and Transparency Explanation Form (CATEF) data collection. The collection of information through CATEF is required by 132 of the Higher Education Act of 1965 as amended (HEA), 20 U.S.C. 1015a. CATEF collects follow-up information from institutions that appear on the tuition and fees and/or net price increase College Affordability and Transparency Center (CATC) Lists for being in the five percent of institutions in their institutional sector that have the highest increases, expressed as a percentage change, over the three-year time period for which the most recent data are available. The information collected through CATEF is used to write a summary report for Congress which is also posted on the CATC website (accessible through the College Navigator). The Department will continue to use two CATEF forms: (1) Net Price and (2) Tuition and Fees.

Dated: May 13, 2024.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2024–10828 Filed 5–16–24; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2024–SCC–0030]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Financial Value Transparency and Gainful Employment Reporting Requirements

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a new information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before June 17, 2024.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link *www.reginfo.gov/public/do/PRAMain* to access the site. Find this information collection request (ICR) by selecting ''Department of Education'' under ''Currently Under Review,'' then check the ''Only Show ICR for Public Comment'' checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the ''View Information Collection (IC) List'' link. Supporting statements and other supporting documentation may be found by clicking on the ''View Supporting Statement and Other Documents'' link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–570–8414.

SUPPLEMENTARY INFORMATION: The Department is especially interested in

public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Financial Value Transparency and Gainful Employment Reporting Requirements.

OMB Control Number: 1845–NEW.

Type of Review: A new ICR.

Respondents/Affected Public: State, Local, and Tribal Governments; Private Sector.

Total Estimated Number of Annual Responses: 284,574.

Total Estimated Number of Annual Burden Hours: 2,300,810.

Abstract: The regulations in § 668.408 in Subpart Q—Financial Value Transparency, that were negotiated in 2022 and the Final Rule published in 2023, establish reporting requirements for postsecondary institutions who participate in the title IV programs under the Higher Education Act of 1965, as amended, to report on their students who enroll in, complete, or withdraw from a gainful employment (GE) program or an eligible non-GE program in specified award years. The new regulations also define the timeframes for institutions to report the required information. This is a new collection. We calculate the average annual burden hours as 2,300,810 for the average 284,574 responses by 4,518 respondents over 3 years. We divided the total 3 year burden hours 6,902,430 by the 853,723 responses to obtain these averages.

Dated: May 14, 2024.

Stephanie Valentine,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2024–10905 Filed 5–16–24; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2024–SCC–0041]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; National Blue Ribbon Schools Program

AGENCY: Office of Communications and Outreach (OCO), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a revision of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before June 17, 2024.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link *www.reginfo.gov/public/do/PRAMain* to access the site. Find this information collection request (ICR) by selecting ''Department of Education'' under ''Currently Under Review,'' then check the ''Only Show ICR for Public Comment'' checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the ''View Information Collection (IC) List'' link. Supporting statements and other supporting documentation may be found by clicking on the ''View Supporting Statement and Other Documents'' link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Aba Kumi, 202–401–1767.

SUPPLEMENTARY INFORMATION: The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: National Blue Ribbon Schools Program.

OMB Control Number: 1860–0506.

Type of Review: A revision of a currently approved ICR.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 420.

Total Estimated Number of Annual Burden Hours: 16,695.

Abstract: Each year since 1982, the U.S. Department of Education's National Blue Ribbon Schools Program has sought out and celebrated great American schools; schools that are demonstrating that all students can achieve to high levels. The purpose of the Program is to honor public and private elementary, middle and high schools based on their overall academic excellence or their progress in closing achievement gaps among different groups of students. The Program is part of a larger U.S. Department of Education effort to identify and disseminate knowledge about best school leadership and teaching practices.

Dated: May 14, 2024.

Stephanie Valentine,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2024–10904 Filed 5–16–24; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: PR24–70–000.

Applicants: Columbia Gas of Kentucky, Inc.

Description: § 284.123 Rate Filing: CKY Baseline Statement of Operating Conditions to be effective 5/13/2024.

Filed Date: 5/13/24.

Accession Number: 20240513–5041.

Comment Date: 5 p.m. ET 6/3/24.

Docket Numbers: RP24–766–000.

Applicants: Iroquois Gas Transmission System, L.P.

Description: § 4(d) Rate Filing: 5.13.24 Negotiated Rates—Emera Energy Services, Inc. R–2715–94 to be effective 6/1/2024.

Filed Date: 5/13/24.

Accession Number: 20240513–5038.

Comment Date: 5 p.m. ET 5/28/24.

Any person desiring to intervene, to protest, or to answer a complaint in any

of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: May 13, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–10880 Filed 5–16–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EF24–5–000]

Southeastern Power Administration; Notice of Filing

Take notice that on May 9, 2024, Southeastern Power Administration submitted a Notice of Cancellation of the JW–2–F Rate Schedule for the sale of power from Southeastern Power Administration's Jim Woodruff Project to Duke Energy Florida to be effective 7/9/2024.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Comment Date: 5:00 p.m. Eastern Time on June 10, 2024.

Dated: May 10, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–10803 Filed 5–16–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER24–1982–000]

Wellesley BESS LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Wellesley BESS LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is May 30, 2024.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*). From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

User assistance is available for eLibrary and the Commission's website during normal business hours from FERC Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov*.

Dated: May 10, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–10800 Filed 5–16–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC24–58–000.

Applicants: Global Infrastructure Management, LLC, BlackRock, Inc.

Description: Supplement to 03/12/2024, Application for Authorization Under Section 203 of the Federal Power Act of Global Infrastructure Management, LLC.

Filed Date: 5/10/24.

Accession Number: 20240510–5248.

Comment Date: 5 p.m. ET 5/20/24.

Docket Numbers: EC24–78–000.

Applicants: Atrisco Energy Storage LLC.

Description: Application for Authorization Under Section 203 of the Federal Power Act of Atrisco Energy Storage LLC.

Filed Date: 5/10/24.

Accession Number: 20240510–5237.

Comment Date: 5 p.m. ET 5/31/24.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER22–1640–003.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Compliance filing: 2024–05–10_Order No. 2222 Compliance Filing to be effective 9/1/2026.

Filed Date: 5/10/24.

Accession Number: 20240510–5179.

Comment Date: 5 p.m. ET 6/10/24.

Docket Numbers: ER23–2977–002.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Tariff Amendment: 2024–05–13_Deficiency Response to Reliability Based Demand Curve to be effective 6/3/2024.

Filed Date: 5/13/24.

Accession Number: 20240513–5246.

Comment Date: 5 p.m. ET 6/3/24.

Docket Numbers: ER24–374–002.

Applicants: PJM Interconnection, L.L.C.

Description: Compliance filing: Compliance Filing to Clarify FTR Bilateral Reform in ER24–374 to be effective 6/30/2024.

Filed Date: 5/13/24.

Accession Number: 20240513–5213.

Comment Date: 5 p.m. ET 6/3/24.

Docket Numbers: ER24–683–001.

Applicants: Duke Energy Carolinas, LLC, Duke Energy Florida, LLC, Duke Energy Progress, LLC.

Description: Compliance filing: Duke Energy Progress, LLC submits tariff filing per 35: Revisions to Attachment M to Joint OATT (SGIP/SGIA) (Order No. 2023–A) to be effective 4/1/2024.

Filed Date: 5/13/24.

Accession Number: 20240513–5129.

Comment Date: 5 p.m. ET 6/3/24.

Docket Numbers: ER24–1248–001.

Applicants: Northern Indiana Public Service Company LLC.

Description: Tariff Amendment: NIPSCO NEET Construction Agreement Deficiency Response to be effective 6/13/2024.

Filed Date: 5/13/24.

Accession Number: 20240513–5189.

Comment Date: 5 p.m. ET 6/3/24.

Docket Numbers: ER24–1674–001.

Applicants: Orange and Rockland Utilities, Inc.

Description: Tariff Amendment: Amendment of O&R 4–1–2024 Undergrounding Filing to be effective 4/1/2024.

Filed Date: 5/13/24.

Accession Number: 20240513–5223.

Comment Date: 5 p.m. ET 6/3/24.

Docket Numbers: ER24–1997–000.

Applicants: Talen Energy Marketing, LLC.

Description: Talen Energy Marketing, LLC submits a One-Time Limited Waiver Request of procedural deadlines in Section 6.6(g) of Attachment DD and Section II.C.2 of Attachment M–Appendix to PJM Interconnection, L.L.C. OATT.

Filed Date: 5/9/24.

Accession Number: 20240509–5233.

Comment Date: 5 p.m. ET 5/30/24.

Docket Numbers: ER24–1998–000.

Applicants: FirstEnergy Service Company, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: FirstEnergy Service Company submits tariff filing per 35.13(a)(2)(iii: FirstEnergy Request for Order Authorizing Abandoned Plant Incentive to be effective 7/15/2024.

Filed Date: 5/13/24.

Accession Number: 20240513–5053.

Comment Date: 5 p.m. ET 6/3/24.

Docket Numbers: ER24–1999–000.

Applicants: All Choice Energy NE LLC.

Description: Baseline eTariff Filing: Market-Based Rate Tariff Application to be effective 5/14/2024.

Filed Date: 5/13/24.

Accession Number: 20240513–5121.

Comment Date: 5 p.m. ET 6/3/24.

Docket Numbers: ER24–2000–000.

Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.

Description: § 205(d) Rate Filing: Alabama Power Company submits tariff filing per 35.13(a)(2)(iii: RWE Solar Development (Dogwood BESS) LGIA Filing to be effective 5/3/2024.

Filed Date: 5/13/24.

Accession Number: 20240513–5123.

Comment Date: 5 p.m. ET 6/3/24.

Docket Numbers: ER24–2001–000

Applicants: Horizon West Transmission, LLC.

Description: § 205(d) Rate Filing: Request for Approval of Transmission Rate Incentives to be effective 7/13/2024.

Filed Date: 5/13/24.

Accession Number: 20240513–5258.

Comment Date: 5 p.m. ET 6/3/24.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES24–37–000.

Applicants: Trans Bay Cable LLC.

Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of Trans Bay Cable LLC.

Filed Date: 5/10/24.

Accession Number: 20240510–5242.

Comment Date: 5 p.m. ET 5/31/24.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing

requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: May 13, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–10881 Filed 5–16–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2311–067]

Great Lakes Hydro America, LLC; Notice of Availability of Draft Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380, the Office of Energy Projects has reviewed the application for license for the Upper Gorham Hydroelectric Project, located on the Androscoggin River in Coos County, New Hampshire and has prepared a Draft Environmental Assessment (DEA) for the project. No federal land is occupied by project works or located within the project boundary.

The DEA contains staff's analysis of the potential environmental impacts of the project and concludes that licensing the project, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

The Commission provides all interested persons with an opportunity to view and/or print the DEA via the internet through the Commission's Home Page (*http://www.ferc.gov/*), using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field, to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* or toll-free at (866) 208–3676, or for TTY, (202) 502–8659.

You may also register online at *https://ferconline.ferc.gov/eSubscription.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Any comments should be filed within 30 days from the date of this notice.

The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* For assistance, please contact FERC Online Support. In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–2300–052.

Any questions regarding this notice may be directed to Ryan Hansen at (202) 502–8074 or *ryan.hansen@ferc.gov.*

Dated: May 10, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–10798 Filed 5–16–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER24–1981–000]

West Warwick Energy Storage 2 LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of West Warwick Energy Storage 2 LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is May 30, 2024.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*). From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

User assistance is available for eLibrary and the Commission's website during normal business hours from FERC Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the

Public Reference Room at *public.referenceroom@ferc.gov.*

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: May 10, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–10801 Filed 5–16–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER24–612–002.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Amendment to Filing, WMPA SA No. 6597; Queue No. AF2–294 to be effective 2/7/2024.

Filed Date: 5/10/24.

Accession Number: 20240510–5117.

Comment Date: 5 p.m. ET 5/31/24.

Docket Numbers: ER24–1424–001.

Applicants: MidAmerican Energy Company.

Description: Tariff Amendment: Joint Pricing Zone Revenue Allocation Agreement (4th Rev)—Amendment to be effective 6/1/2024.

Filed Date: 5/10/24.

Accession Number: 20240510–5060.

Comment Date: 5 p.m. ET 5/31/24.

Docket Numbers: ER24–1987–000.

Applicants: PJM Interconnection, L.L.C.

Description: 205(d) Rate Filing: GDECS Revisions to PJM Tariff, OA & RAA, 5-Day Comment Period & Waiver to be effective 5/31/2024.

Filed Date: 5/10/24.

Accession Number: 20240510–5037.

Comment Date: 5 p.m. ET 5/17/24.

Docket Numbers: ER24–1988–000.

Applicants: PJM Interconnection, L.L.C.

Description: 205(d) Rate Filing: Revisions to RAA Definitions regarding Dual Fuel Class to be effective 7/10/2024.

Filed Date: 5/10/24.

Accession Number: 20240510–5074.

Comment Date: 5 p.m. ET 5/31/24.

Docket Numbers: ER24–1989–000.

Applicants: PJM Interconnection, L.L.C.

Description: 205(d) Rate Filing: Amendment to ISA, SA No. 6431; AE1–243 to be effective 7/10/2024.

Filed Date: 5/10/24.

Accession Number: 20240510–5088.

Comment Date: 5 p.m. ET 5/31/24.

Docket Numbers: ER24–1990–000.

Applicants: PJM Interconnection, L.L.C.

Description: 205(d) Rate Filing: Designated Entity Agreement, SA No. 7226 between PJM and PSEG RT to be effective 4/11/2024.

Filed Date: 5/10/24.

Accession Number: 20240510–5089.

Comment Date: 5 p.m. ET 5/31/24.

Docket Numbers: ER24–1991–000.

Applicants: ISO New England Inc.

Description: ISO New England Inc. Submits Capital Budget Quarterly Filing for First Quarter of 2024.

Filed Date: 5/10/24.

Accession Number: 20240510–5115.

Comment Date: 5 p.m. ET 5/31/24.

Docket Numbers: ER24–1992–000.

Applicants: PJM Interconnection, L.L.C.

Description: 205(d) Rate Filing: Original GIA, Service Agreement No. 7233; AG1–348 to be effective 4/10/2024.

Filed Date: 5/10/24.

Accession Number: 20240510–5114.

Comment Date: 5 p.m. ET 5/31/24.

Docket Numbers: ER24–1993–000.

Applicants: NorthWestern Corporation.

Description: Compliance filing: Order 2023 Compliance Filing—LGIP & SGIP to be effective 7/10/2024.

Filed Date: 5/10/24.

Accession Number: 20240510–5123.

Comment Date: 5 p.m. ET 5/31/24.

Docket Numbers: ER24–1994–000.

Applicants: Public Power (PA), LLC.

Description: Tariff Amendment: Cancellation entire tariff to be effective 5/11/2024.

Filed Date: 5/10/24.

Accession Number: 20240510–5134.

Comment Date: 5 p.m. ET 5/31/24.

Docket Numbers: ER24–1995–000.

Applicants: PJM Interconnection, L.L.C.

Description: 205(d) Rate Filing: Revisions to Tariff, Attachment L re: OVEC Legal Name to be effective 7/10/2024.

Filed Date: 5/10/24.

Accession Number: 20240510–5135.

Comment Date: 5 p.m. ET 5/31/24.

Docket Numbers: ER24–1996–000.

Applicants: PJM Interconnection, L.L.C.

Description: 205(d) Rate Filing: Revisions to CTOA re: OVEC Legal Name to be effective 7/10/2024.

Filed Date: 5/10/24.

Accession Number: 20240510–5155.

Comment Date: 5 p.m. ET 5/31/24.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

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Dated: May 10, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–10805 Filed 5–16–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER24–1983–000]

West Warwick Energy Storage 3 LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of West Warwick Energy Storage 3 LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is May 30, 2024.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

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Dated: May 10, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–10799 Filed 5–16–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER24–1980–000]

West Warwick Energy Storage 1 LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of West Warwick Energy Storage 1 LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is May 30, 2024.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*). From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

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communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: May 10, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–10802 Filed 5–16–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 10615–058]

Tower Kleber Limited Partnership; Notice of Application Accepted for Filing, Soliciting Motions To Intervene and Protests, Ready for Environmental Analysis, and Soliciting Comments, Recommendations, Terms and Conditions, and Prescriptions

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.

b. *Project No.:* 10615–058.

c. *Date Filed:* April 28, 2022.

d. *Applicant:* Tower Kleber Limited Partnership (Tower Kleber).

e. *Name of Project:* Tower and Kleber Hydroelectric Project (project).

f. *Location:* On the Black River in Cheboygan County, Michigan.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791 (a)–825(r).

h. *Applicant Contact:* Ms. Tiffany Heon, Tower Kleber Limited Partnership, A–121 Strachan Street, Port Hope, Ontario, Canada L1A 1J1; telephone at (647) 220–4476; email at *tiffanyheon@hotmail.com.*

i. *FERC Contact:* Arash Barsari, Project Coordinator, Great Lakes Branch, Division of Hydropower Licensing; telephone at (202) 502–6207; email at *Arash.JalaliBarsari@ferc.gov.*

j. *Deadline for filing motions to intervene and protests, comments, recommendations, terms and conditions, and prescriptions:* 60 days from the issuance date of this notice; reply comments are due 105 days from the issuance date of this notice.

The Commission strongly encourages electronic filing. Please file motions to intervene and protests, comments, recommendations, terms and conditions, and prescriptions using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852. All filings must clearly identify the project name and docket number on the first page: Tower and Kleber Hydroelectric Project (P–10615–058).

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted for filing and is now ready for environmental analysis.

l. *Project Description:* The project consists of two hydropower developments, the Tower Development and the Kleber Development.

The Tower Development consists of an approximately 738-foot-long, 22.75-foot-high concrete gravity dam that includes: (1) a 2-foot-long west abutment section; (2) a 362.6-foot-long non-overflow earthen embankment with a concrete core wall; (3) a 198.3-foot-long non-overflow concrete embankment section; (4) a 110-foot-long spillway section with a crest elevation of 722.2 feet National Geodetic Vertical Dam of 1929 (NGVD 29); (5) a 35.3-foot-long intake structure with four 6.67-foot-wide, 10.83-foot-high wooden sluice gates each equipped with a 7.73-foot-wide, 15.5-foot-high trashrack with 1.25-inch clear bar spacing; and (6) a 30-foot-long east earthen abutment section. The Tower Development dam creates an impoundment with a surface area of 83 acres at a normal maximum surface elevation of 722.1 feet NGVD 29.

From the impoundment, water flows through the intake structure to two 280-kilowatt (kW) Francis turbine-generators located in a 32.5-foot-long, 35.3-foot-wide powerhouse. Water is discharged from the turbines to a tailrace. Electricity generated at the Tower Development is transmitted to the electric grid via an 87-foot-long, 2.4-kilovolt (kV) underground generator lead line, a 2.4/12.5-kV step-up transformer, and a 330-foot-long, 12.5-kV underground transmission line.

Project recreation facilities at the Tower Development include: (1) a boat access site and parking area approximately 1,300 feet upstream of the dam on the western shore of the impoundment; (2) a canoe take-out site at the earthen embankment; (3) an approximately 270-foot-long canoe portage route; (4) a canoe put-in site approximately 75 feet downstream of the dam; (5) a handicapped-accessible fishing site and parking area approximately 700 feet upstream of the dam on the western shore of the impoundment; and (6) an approximately 370-foot-long tailrace access footpath from the parking area of the fishing site to the canoe portage route.

The Kleber Development consists of an approximately 535-foot-long, 45.4-foot-high dam that includes: (1) an approximately 320-foot-long west earthen embankment; (2) a 44.5-foot-long reinforced concrete section that includes: (a) a 12-foot-long ogee spillway with a crest elevation of 689.1 feet NGVD 29 and equipped with an approximately 12-foot-wide, 13-foot-high Tainter gate that has a crest elevation of 702.1 feet NGVD 29; and (b) two 11-foot-wide, 11-foot-high intake gates each equipped with a trashrack with 2.56-inch clear bar spacing; and (3) an approximately 170-foot-long east earthen embankment. The Kleber Development dam creates an impoundment with a surface area of 267 acres at a normal maximum surface elevation of 701.1 feet NGVD 29.

From the impoundment, water flows through the Tainter gate to a 154-foot-long concrete spillway chute and a 30-foot-long, 30-foot-wide stilling basin that provides flow to the Black River downstream of the dam. From the impoundment, water also flows through the two intake gates to a 139.7-foot-long, 7-foot-diameter penstock and a 139.3-foot-long, 7-foot-diameter penstock that provide flow to two 600-kW Kaplan turbine-generators in a 40-foot-long, 42-foot-wide powerhouse. Water is discharged from the turbines to a tailrace. The Kleber Development also includes an emergency spillway with a 200-foot-long concrete weir that has a

crest elevation of approximately 702.0 feet NGVD 29. Electricity generated at the Kleber Development is transmitted to the electric grid via a 168-foot-long, 2.4-kV generator lead line and a 2.4/12.5-kV step-up transformer.

Project recreation facilities at the Kleber Development include: (1) a boat access site and parking area approximately 4,000 feet upstream of the dam on the eastern shore of the impoundment; (2) a canoe take-out site approximately 70 feet upstream of the dam on the east shoreline of the impoundment; (3) an approximately 580-foot-long canoe portage trail; (4) a tailrace access road and canoe put-in site on the southern shore of the Black River approximately 400 feet downstream of the dam; and (5) a tailrace access site and parking area on the northern shore of the Black River approximately 180 feet downstream of the dam.

The average annual energy production of the project from 2017 through 2021 was 7,742 MWh.

The current license requires Tower Kleber to: (1) operate the project in a run-of-river mode, such that project outflow approximates inflow; (2) maintain an impoundment elevation of 722.1 NGVD 29 for the Tower Development and 701.1 feet NGVD 29 for the Kleber Development, and limit impoundment fluctuations to no more than +/− 0.25 foot; (3) limit impoundment drawdowns to no more than 1 foot from November 1 through March 31; (4) protect and enhance lake sturgeon and lake sturgeon habitat in the Black River Basin in accordance with a March 1, 1994 settlement agreement between the licensee and Michigan Department of Natural Resources (DNR); (5) operate and maintain all project recreation facilities; (6) protect and monitor water quality and bald eagles; and (7) monitor invasive species. In 2009, Tower Kleber constructed the Black River Streamside Rearing Facility (Rearing Facility) and pumping station north of the Kleber Development dam to comply with the license requirement to protect and enhance lake sturgeon in the Black River Basin. The Rearing Facility and pumping station are owned and maintained by Tower Kleber, and managed by the Michigan DNR and Michigan State University (MSU) to rear lake sturgeon that are stocked primarily at Black Lake, Mullett Lake, and Burt Lake.

Tower Kleber proposes to revise the project boundary to include the following existing project facilities: (1) the emergency spillway at the Kleber Development; (2) the tailrace access road and canoe portage trail at the Kleber Development; (3) the boat access site and parking area approximately 4,000 feet upstream of the Kleber Development dam; (4) the entire transmission line of the Tower Development; and (5) the entire tailrace access footpath at the Tower Development. Tower Kleber also proposes to revise the project boundary to include approximately 0.3 acre of land associated with a camping and fishing access approximately 6,000 feet upstream of the Kleber Development dam that is owned by the State of Michigan. Tower Kleber proposes to remove the following land parcels from the current project boundary: (1) an approximately 8-acre area adjacent to the east and west shorelines of the Black River from approximately 700 feet upstream to 900 feet downstream of the Tower Development dam; (2) an approximately 10-acre area northeast of the east earthen embankment of the Kleber Development; and (3) an approximately 0.2-acre area south of the emergency spillway at the Kleber Development.

Tower Kleber proposes to: (1) continue to operate the project in a run-of-river mode; (2) continue to maintain an impoundment elevation of 722.1 NGVD 29 for the Tower Development and 701.1 feet NGVD 29 for the Kleber Development, and limit impoundment fluctuations to no more than +/− 0.25 foot; (3) continue to limit impoundment drawdowns to no more than 1 foot from November 1 through March 31; (4) maintain the Rearing Facility and pumping station as project facilities so that Michigan DNR and MSU can continue to rear lake sturgeon at the Rearing Facility (*i.e.,* Tower Kleber is not proposing to rear lake sturgeon, but is proposing to maintain the facilities needed to rear lake sturgeon); (5) monitor project flows; (6) monitor invasive species five years after any license issued and every ten years thereafter; (7) install and maintain invasive species signage for zebra mussels at the boat launch areas to encourage boaters, canoeists, and kayakers to clean their boats and not transport water or vegetation upstream; (8) monitor dissolved oxygen, sediment, and mercury in the impoundments; and (9) continue to operate and maintain project recreation facilities *that are on land currently owned by Tower Kleber.*

Tower Kleber is not proposing to operate and maintain the following existing project recreation facilities that are required by the current license: (1) the boat access site and associated parking area approximately 4,000 feet upstream of the Kleber Development dam that is located on land owned by the State of Michigan; and (2) the boat access site and parking area approximately 1,300 feet upstream of the Tower Development dam that is located on land owned by the Forest Township.

m. A copy of the application can be viewed on the Commission's website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document (*i.e.,* P–10615). For assistance, contact FERC Online Support.

n. Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, and .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

All filings must (1) bear in all capital letters the title ''PROTEST,'' ''MOTION TO INTERVENE,'' ''COMMENTS,'' ''REPLY COMMENTS,'' ''RECOMMENDATIONS,'' ''TERMS AND CONDITIONS,'' or ''PRESCRIPTIONS;'' (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name of the person submitting the filing; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed on the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

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others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

You may also register online at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

o. The applicant must file no later than 60 days following the date of issuance of this notice: (1) a copy of the water quality certification; (2) a copy of the request for certification, including proof of the date on which the certifying agency received the request; or (3) evidence of waiver of water quality certification.

p. *Procedural schedule:* The application will be processed according to the following schedule. Revisions to the schedule will be made as appropriate.

Milestone	Target date
Filing of Comments, Recommendations, Terms and Conditions, and Prescriptions.	July 2024.
Filing of Reply Comments	August 2024.

q. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of this notice.

Dated: May 10, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–10797 Filed 5–16–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP24–765–000.

Applicants: BBT Trans-Union Interstate Pipeline, L.P.

Description: 4(d) Rate Filing: BBT Trans Union Upstream OBA Revenues/Costs to be effective 6/1/2024.

Filed Date: 5/10/24.

Accession Number: 20240510–5001.

Comment Date: 5 p.m. ET 5/22/24.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: May 10, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–10804 Filed 5–16–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP24–466–000]

Gulf South Pipeline Company, LLC; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on May 3, 2024, Gulf South Pipeline Company, LLC (Gulf South), 9 Greenway Plaza, Suite 800, Houston, Texas 77046, filed in the above referenced docket, a prior notice request pursuant to sections 157.205 and 157.216(b) of the Commission's regulations under the Natural Gas Act (NGA), and Gulf South's blanket certificate issued in Docket No. CP82–430–000, for authorization to abandon in place and partially by removal its Mineola Compressor Station located in Wood County, Texas (Mineola Compressor Station Abandonment Project). Specifically, Gulf South proposes to disconnect and remove all above-ground facilities and concrete pipe supports; and abandon in place two 330 horsepower compressor units, compressor and storage buildings, and appurtenant auxiliary facilities. The project is in response to reductions in demand for transportation services by Gulf South's customers in the area. Gulf South no longer needs the facilities in order to continue to provide firm transportation service, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*). From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

User assistance is available for eLibrary and the Commission's website during normal business hours from FERC Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

Any questions concerning this request should be directed to Juan Eligio, Jr., Manager of Regulatory Affairs, Gulf South Pipeline Company, LLC, 9 Greenway Plaza, Houston, Texas, 77046, at (713) 479–3480 or by email to *juan.eligio@bwpipelines.com.*

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file a protest to the project, you can file a motion to intervene in the proceeding, and you can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5 p.m. eastern time on July 12, 2024. How to

file protests, motions to intervene, and comments is explained below.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,[1] any person [2] or the Commission's staff may file a protest to the request. If no protest is filed within the time allowed or if a protest is filed and then withdrawn within 30 days after the allowed time for filing a protest, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request for authorization will be considered by the Commission.

Protests must comply with the requirements specified in section 157.205(e) of the Commission's regulations,[3] and must be submitted by the protest deadline, which is July 12, 2024. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

Interventions

Any person has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure [4] and the regulations under the NGA [5] by the intervention deadline for the project, which is July 12, 2024. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

All timely, unopposed motions to intervene are automatically granted by operation of Rule 214(c)(1). Motions to intervene that are filed after the intervention deadline are untimely and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations. A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Comments

Any person wishing to comment on the project may do so. The Commission considers all comments received about the project in determining the appropriate action to be taken. To ensure that your comments are timely and properly recorded, please submit your comments on or before July 12, 2024. The filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding.

How To File Protests, Interventions, and Comments

There are two ways to submit protests, motions to intervene, and comments. In both instances, please reference the Project docket number CP24–466–000 in your submission.

(1) You may file your protest, motion to intervene, and comments by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Protest'', ''Intervention'', or ''Comment on a Filing''; or [6]

(2) You can file a paper copy of your submission by mailing it to the address below. Your submission must reference the Project docket number CP24–466–000.

To file via USPS: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other method: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of submissions (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Protests and motions to intervene must be served on the applicant either by mail or email (with a link to the document) at: Juan Eligio, Jr., Manager of Regulatory Affairs, Gulf South Pipeline Company, LLC, 9 Greenway Plaza, Houston, Texas 77046, or by email to *juan.eligio@bwpipelines.com.* Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Dated: May 13, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–10878 Filed 5–16–24; 8:45 am]

BILLING CODE 6717–01–P

[1] 18 CFR 157.205.

[2] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[3] 18 CFR 157.205(e).

[4] 18 CFR 385.214.

[5] 18 CFR 157.10.

[6] Additionally, you may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project.

ENVIRONMENTAL PROTECTION AGENCY

[FRL OP–OFA–126]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS)

Filed May 6, 2024 10 a.m. EST Through May 13, 2024 10 a.m. EST

Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxapps.epa.gov/cdx-enepa-II/public/action/eis/search.*

EIS No. 20240080, Final Supplement, BLM, WY, Buffalo Field Office Final Supplemental Environmental Impact Statement and Proposed Resource Management Plan, Review Period Ends: 06/17/2024, Contact: Thomas Bills 307–684–1133.

EIS No. 20240081, Final Supplement, BLM, MT, Miles City Field Office Final Supplemental Environmental Impact Statement and Proposed Resource Management Plan, Review Period Ends: 06/17/2024, Contact: Irma Nansel 406–233–3653.

EIS No. 20240082, Final, NRCS, WI, Coon Creek Watershed, Review Period Ends: 06/17/2024, Contact: Joshua Odekirk 262–470–2064.

EIS No. 20240083, Final, NRCS, WI, West Fork Kickapoo Watershed, Review Period Ends: 06/17/2024, Contact: Joshua Odekirk 262–470–2064.

Dated: May 13, 2024.

Cindy S. Barger,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2024–10857 Filed 5–16–24; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Notice of Board Meeting; Correction

AGENCY: Federal Retirement Thrift Investment Board.

ACTION: Notice; correction.

SUMMARY: The FRTIB published a document in the **Federal Register** of May 13, 2024, concerning a notice of its May 2024 Board Meeting. The notice inadvertently omitted language regarding written statements submitted prior to the meeting.

FOR FURTHER INFORMATION CONTACT: Kimberly Weaver, Director, Office of External Affairs, (202) 942–1640.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of May 13, 2024, in FR Doc 2024–10338, on page 41436, add the following language between the entry for Closed Session and Authority:

Written Statements: Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and section 10(a)(3) of the Federal Advisory Committee Act, interested parties may submit written statements in response to the stated agenda of the meeting, or to the Employee Thrift Advisory Council (ETAC), in general. Individuals may submit their comments to *ETACComments@frtib.gov.* Written comments or statements received less than 5 days before ETAC's meeting may not be provided to the Committee until its next meeting.

Dated: May 14, 2024.

Dharmesh Vashee,

General Counsel.

[FR Doc. 2024–10911 Filed 5–16–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–24–1408]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) received approval from the Office of Management and Budget (OMB) to conduct the National Center for Health Statistics (NCHS) Rapid Surveys System (RSS) (OMB Control No. 0920–1408), which includes fielding four surveys per year. Round 1 Survey was approved in June 2023. A second, third, and fourth round of the RSS were additionally approved. In accordance with the Terms of Clearance, NCHS will publish a 30-day **Federal Register** Notice announcing each new survey so that public comments can be received about the specific content of each survey. This notice includes specific details about the questions that would be asked in the fifth round (Round 5) of the RSS and serves to allow 30 days for public and affected agency comments, consistent with OMB's terms of clearance.

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

Rapid Surveys System (RSS) Round 5 (OMB Control No. 0920–1408)—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC),

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C.), as amended, authorizes that the Secretary of Health and Human Services (HHS), acting through NCHS, collect data about the health of the population of the United States. The Rapid Surveys

System (RSS) (OMB Control No. 0920–1408) collects data on emerging public health topics, attitudes, and behaviors using cross-sectional samples from two commercially available, national probability-based online panels. The RSS then combines these data to form estimates that approximate national representation in ways that many data collection approaches cannot. The RSS collects data in contexts in which decision makers' need for time-sensitive data of known quality about emerging and priority health concerns is a higher priority than their need for statistically unbiased estimates.

The RSS complements NCHS's current household survey systems. As quicker turnaround surveys that require less accuracy and precision than CDC's more rigorous population representative surveys, the RSS incorporates multiple mechanisms to carefully evaluate the resulting survey data for their appropriateness for use in public health surveillance and research (*e.g.,* hypothesis generating) and facilitates continuous quality improvement by supplementing these panels with intensive efforts to understand how well the estimates reflect populations at most risk. The RSS data dissemination strategy communicates the strengths and limitations of data collected through online probability panels as compared to more robust data collection methods. The RSS has three major goals: (1) to provide CDC and other partners with time-sensitive data of known quality about emerging and priority health concerns; (2) to use these data collections to continue NCHS's evaluation of the quality of public health estimates generated from commercial online panels; and (3) to improve methods to communicate the appropriateness of public health estimates generated from commercial online panels.

The RSS is designed to have four rounds of data collection each year with data being collected by two contractors with probability panels. A cross-sectional nationally representative sample will be drawn from the online probability panel maintained by each of the contractors. As part of the base (minimum sample size), each round of data collection will collect 2,000 responses per quarter. The RSS can be expanded by increasing the number of completed responses per round or the number of rounds per year as needed up to a maximum of 28,000 responses per year per contractor or 56,000 total responses per year. Additionally, each data collection may include up to 2,000 additional responses per quarter (8,000 for the year) to improve representativeness. This increases the maximum burden by up to 16,000 responses per year. The RSS may also target individual surveys to collect data only from specific subgroups within existing survey panels and may supplement data collection for such groups with additional respondents from other probability or nonprobability samples. An additional 12,000 responses per year may be used for these developmental activities.

Each round's questionnaire will consist of four main components: (1) basic demographic information on respondents to be used as covariates in analyses; (2) new, emerging, or supplemental content proposed by NCHS, other CDC Centers, Institute, and Offices, and other HHS agencies; (3) questions used for calibrating the survey weights; and (4) additional content selected by NCHS to evaluate against relevant benchmarks. NCHS will use questions from Components 1 and 2 provide relevant, timely data on new, emerging, and priority health topics to be used for decision making. NCHS will use questions from Components 3 and 4 to weight and evaluate the quality of the estimates coming from questions in Components 1 and 2. NCHS submits a 30-day **Federal Register** Notice with information on the contents of each round of data collection.

NCHS calibrates survey weights from the RSS to gold standard surveys. Questions used for calibration in this round of RSS will include chronic conditions, social and work limitation, civic engagement, language used at home and in other settings and marital status. All of these questions have been on the National Health Interview Survey (NHIS) in prior years allowing calibration to these data.

Finally, all RSS rounds will include several questions that were previously on NHIS or other NCHS surveys, or other suitable federal surveys for benchmarking to evaluate data quality. Panelists in the RSS will be asked about health status, chronic conditions, developmental delay and disability, anxiety and depression, injury, COVID, healthcare access and utilization, health insurance, stressful life events for the selected child and social determinates including ability to pay medical bill, SNAP participation, and food insecurity at a family or household level.

Round 5 will include content on positive childhood experiences and childhood vaccinations. Both topics are in support of the CDC's 2023–2024 Collaborative Initiative of Supporting Young Families. The questions in Round 5 will be answered by panelists who are a parent/guardian of one randomly sampled child in the household. Interested persons are invited to send comments regarding this information collection, including ways to enhance the quality, utility, and clarity of the Round 5 content on positive childhood experience and childhood vaccinations.

The NCHS RSS Round 5 data collection is based on 8,000 complete surveys and is estimated to be 2,687 hours. 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)
Adults 18+	Survey: NCHS RSS Round 5	8,000	1	20/60
Adult 18+	Cognitive Interviews	20	1	1

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2024–10877 Filed 5–16–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health, National Institute for Occupational Safety and Health; Correction

AGENCY: Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice; correction.

SUMMARY: Notice is hereby given of a change in the meeting of the Advisory Board on Radiation and Worker Health, National Institute for Occupational Safety and Health (ABRWH); April 17, 2024, 9:15 a.m. to 6 p.m. EDT, teleconference/web conference, in the original **Federal Register** notice. The meeting notice was published in the **Federal Register** on March 4, 2024 and is being corrected to change the executive order number in Supplementary Information.

FOR FURTHER INFORMATION CONTACT: Rashaun Roberts, Ph.D., Designated Federal Officer, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1090 Tusculum Avenue, Mailstop C–24, Cincinnati, Ohio 45226, Telephone (513) 533–6800, Toll Free 1(800) CDC–INFO, Email: *ocas@cdc.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 4, 2024, in FR Doc. 2024–04431 at 89 FR 15580, in the third column, correct the **SUPPLEMENTARY INFORMATION** caption to read:

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC). In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC.

The charter was issued on August 3, 2001, renewed at appropriate intervals, and rechartered under Executive Order 14109 on September 29, 2023. Unless continued by the President the Board will terminate on September 30, 2025, consistent with E.O. 14109 of September 29, 2023.

The Director, Office of Strategic Business Initiatives, 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, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2024–10830 Filed 5–16–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health, National Institute for Occupational Safety and Health; Correction

AGENCY: Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice; correction.

SUMMARY: Notice is hereby given of a change in the meeting of the Advisory Board on Radiation and Worker Health, National Institute for Occupational Safety and Health (ABRWH); December 7, 2023, 11 a.m. to 6 p.m. EST, teleconference/web conference, in the original **Federal Register** notice. The meeting notice was published in the **Federal Register** on November 17, 2023. The meeting notice is being corrected to change the executive order number.

FOR FURTHER INFORMATION CONTACT: Rashaun Roberts, Ph.D., Designated Federal Officer, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1090 Tusculum Avenue, Mailstop C–24, Cincinnati, Ohio 45226, Telephone (513) 533–6800, Toll Free 1(800) CDC–INFO, Email: *ocas@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of November 17, 2023, in FR Doc. 2023–25460, on page 80304, in the third column, correct the ''Supplementary Information'' caption to read:

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC). In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC.

The charter was issued on August 3, 2001, renewed at appropriate intervals, and rechartered under Executive Order 14109 on September 29, 2023. Unless continued by the President the Board will terminate on September 30, 2025, consistent with E.O. 14109 of September 29, 2023.

The Director, Office of Strategic Business Initiatives, 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, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2024–10831 Filed 5–16–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Meeting of the Advisory Board on Radiation and Worker Health (ABRWH), Subcommittee for Procedure Reviews, National Institute for Occupational Safety and Health (NIOSH)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC) announces the following meeting of the Subcommittee for Procedure Reviews (SPR) of the Advisory Board on Radiation and Worker Health (ABRWH or the Advisory Board). This meeting is open to the public, but without a public comment period. The public is welcome to submit written comments in advance of the meeting, to the contact person below. Written comments received in advance of the meeting will be included in the official record of the meeting. The public is also welcomed to listen to the meeting by joining the audio conference (information below). The audio conference line has 150 ports for callers.

DATES: The meeting will be held on July 30, 2024, from 11 a.m. to 4:30 p.m., EDT. Written comments must be received on or before July 21, 2024.

ADDRESSES: You may submit comments by mail to: Rashaun Roberts, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1090 Tusculum Avenue, MS C–24, Cincinnati, Ohio 45226.

FOR FURTHER INFORMATION CONTACT: Rashaun Roberts, Ph.D., Designated Federal Officer, National Center for Occupational Safety and Health, Centers for Disease Control and Prevention, 1090 Tusculum Avenue, Mailstop C–24, Cincinnati, Ohio 45226, Telephone: (513) 533–6800, Toll Free 1(800) CDC–INFO, Email: *ocas@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC). In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC.

The charter was issued on August 3, 2001, renewed at appropriate intervals, and rechartered under Executive Order 14109 on September 29, 2023. Unless continued by the President the Board will terminate on September 30, 2025, consistent with E.O. 14109 of September 29, 2023.

Purpose: The Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class. The ABRWH Subcommittee on Procedure Reviews (SPR) is responsible for overseeing, tracking, and participating in the reviews of all procedures used in the dose reconstruction process by the NIOSH Division of Compensation Analysis and Support (DCAS) and its dose reconstruction contractor (Oak Ridge Associated Universities—ORAU).

Matters to be Considered: The meeting agenda will include discussions on the following: 1. Carry-over items from March 14, 2024, SPR meeting, including a. DCAS–PER–040 ''Mallinckrodt TBD Revisions,'' b. DCAS–PER–068 ''Electro Metallurgical Co,'' c. DCAS–PER–070 ''Nuclear Metals Inc.,'' d. DCAS–PER–072 ''Seymour Specialty Wiring Co,'' e. ORAUT–RPRT–0060 ''Neutron Dose from Highly Enriched Uranium,'' and f. DR template reviews—findings versus observations. 2. Newly-issued SC&A reviews, including a. ORAUT–OTIB–0036 ''Internal Dosimetry Coworker Data for Portsmouth Gaseous Diffusion Plant,'' b. ORAUT–OTIB–0040 ''External Coworker Dosimetry Data for the Portsmouth Gaseous Diffusion Plant,'' c. ORAUT–OTIB–0093 ''Conversion of Committed Effective Dose to Annual Organ Dose,'' and d. ORAUT–RPRT–0087 ''Applications of Regression in External Dose Reconstruction.''; 3. Preparation for August 2024 Full ABRWH Meeting: Review of technical guidance documents ready for full Board approval; 4. Newly-Issued Guidance and Supplemental Topics. Agenda items are subject to change as priorities dictate. For additional information, please contact Toll Free 1(800) 232–4636.

Meeting Information: Audio Conference Call via FTS Conferencing. The USA toll-free dial-in number is 1–866–659–0537; the pass code is 9933701.

The Director, Office of Strategic Business Initiatives, 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, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2024–10834 Filed 5–16–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Immunization Practices (ACIP); 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 Immunization Practices (ACIP), Centers for Disease Control and Prevention, Department of Health and Human Services, has been renewed for a 2-year period through April 1, 2026.

FOR FURTHER INFORMATION CONTACT: Melinda Wharton, M.D., M.P.H., Designated Federal Officer, Advisory Committee on Immunization Practices, Centers for Disease Control and Prevention, Department of Health and Human Services, 1600 Clifton Road NE, MS H24–8, Atlanta, Georgia 30329–4027, telephone (404) 639–8755, or fax (404) 471–8347.

SUPPLEMENTARY INFORMATION: CDC is providing notice under 5 U.S.C. 1001–1014 of the renewal of the charter of the Advisory Committee on Immunization Practices, Centers for Disease Control and Prevention, Department of Health and Human Services. This charter has been renewed for a two-year period through April 1, 2026.

The Director, Office of Strategic Business Initiatives, 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, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2024–10835 Filed 5–16–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health, National Institute for Occupational Safety and Health; Correction

AGENCY: Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice; correction.

SUMMARY: Notice is hereby given of a change in the meeting of the Advisory Board on Radiation and Worker Health, National Institute for Occupational Safety and Health (ABRWH); February 14, 2024, 11 a.m. to 1 p.m. EST, teleconference/web conference, in the original **Federal Register** notice. The meeting notice was published in the **Federal Register** on December 18, 2023. The meeting notice is being corrected to change the executive order number.

FOR FURTHER INFORMATION CONTACT: Rashaun Roberts, Ph.D., Designated Federal Officer, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1090 Tusculum Avenue, Mailstop C–24, Cincinnati, Ohio 45226, Telephone (513) 533–6800, Toll Free 1(800) CDC–INFO, Email: *ocas@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of December 18, 2023, in FR Doc. 2023–27716, on page 87429, in the first column, correct the **SUPPLEMENTARY INFORMATION** caption to read:

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC). In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC.

The charter was issued on August 3, 2001, renewed at appropriate intervals, and rechartered under Executive Order 14109 on September 29, 2023. Unless continued by the President the Board will terminate on September 30, 2025, consistent with E.O. 14109 of September 29, 2023.

The Director, Office of Strategic Business Initiatives, 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, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2024–10832 Filed 5–16–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health, National Institute for Occupational Safety and Health; Correction

AGENCY: Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice; correction.

SUMMARY: Notice is hereby given of a change in the meeting of the Advisory Board on Radiation and Worker Health, National Institute for Occupational Safety and Health (ABRWH); June 26, 2024, 11 a.m. to 1 p.m. EDT, teleconference/web conference, in the original **Federal Register** notice. The meeting notice was published in the **Federal Register** on April 15, 2024 and is being corrected to change the executive order number in **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Rashaun Roberts, Ph.D., Designated Federal Officer, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1090 Tusculum Avenue, Mailstop C–24, Cincinnati, Ohio 45226, Telephone (513) 533–6800, Toll Free 1(800) CDC–INFO, Email: *ocas@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of April 15, 2024, in FR Doc. 2024–07847 at 89 FR 26152, in the second column, correct the **SUPPLEMENTARY INFORMATION** caption to read:

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines that

have been promulgated by the Department of Health and Human Services (HHS) as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC). In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC.

The charter was issued on August 3, 2001, renewed at appropriate intervals, and rechartered under Executive Order 14109 on September 29, 2023. Unless continued by the President the Board will terminate on September 30, 2025, consistent with E.O. 14109 of September 29, 2023.

The Director, Office of Strategic Business Initiatives, 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, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2024–10833 Filed 5–16–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10307]

Agency Information Collection Activities: Proposed Collection; 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by July 16, 2024.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10307 Medical Necessity and Claims Denial Disclosures Under MHPAEA

Under the 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 requires federal agencies to publish a 60-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.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medical Necessity and Claims Denial Disclosures under MHPAEA; *Use:* The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) (Pub. L.110–343) generally requires that group health plans and group health insurance issuers offering both medical and surgical (med/surg) and mental health or substance use disorder (MH/SUD) benefits do not apply any more restrictive financial requirements (*e.g.,* co-pays, deductibles) and/or treatment limitations (*e.g.,* visit limits) to MH/SUD benefits than those requirements and/or limitations applied to substantially all med/surg benefits. The Patient Protection and Affordable Care Act, Public Law 111–148, was enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010, Public Law 111–152, was enacted on March 30, 2010. These statutes are collectively known as the ''Affordable Care Act'' (ACA). The ACA extended MHPAEA to apply to the individual health insurance market. Additionally, the Department of Health and Human Services (HHS) final regulation regarding essential health benefits (EHB) requires health insurance issuers offering non-grandfathered health insurance coverage in the individual and small group markets, through an Exchange or outside of an Exchange, to comply with the requirements of the MHPAEA regulations to satisfy the

requirement to cover EHB (45 CFR 147.150 and 156.115).

Medical Necessity Disclosure Under MHPAEA

MHPAEA specifically amends the Public Health Service (PHS) Act to require plan administrators or health insurance issuers to provide, upon request, the criteria for medical necessity determinations made with respect to MH/SUD benefits to current or potential participants, beneficiaries, or contracting providers. The Final Rules under MHPAEA set forth rules for providing criteria for medical necessity determinations. CMS administers MHPAEA with respect to self-insured, non-Federal governmental plans in all States, and health insurance issuers in two States.

Claims Denial Disclosure Under MHPAEA

MHPAEA specifically amends the PHS Act to require plan administrators or health insurance issuers to provide, upon request, the reason for any denial or reimbursement of payment for MH/SUD services to the participant or beneficiary involved in the case. The Final Rules under MHPAEA at 45 CFR 146.136(d)(2) implement MHPAEA. CMS administers MHPAEA with respect to self-insured, non-Federal governmental plans in all States and health insurance issuers in two States, and the regulation provides a safe harbor such that non-Federal governmental plans (and issuers offering coverage in connection with such plans) are deemed to comply with requirements of paragraph (d)(2) of 45 CFR 146.136 if they provide the reason for claims denial in a form and manner consistent with ERISA requirements found in 29 CFR 2560.503–1. Section 146.136(d)(3) clarifies that PHS Act section 2719 governing internal claims and appeals and external review as implemented by 45 CFR 147.136, covers MHPAEA claims denials and requires that, when a non-quantitative treatment limitation (NQTL) is the basis for a claims denial, that a non-grandfathered plan or issuer must provide the processes, strategies, evidentiary standard, and other factors used in developing and applying the NQTL with respect to med/surg benefits and MH/SUD benefits.

Disclosure Request Form

Group health plan participants, beneficiaries, covered individuals in the individual market, or persons acting on their behalf, may use this optional model form to request information from plans regarding the medical necessity and claims denials disclosures referenced above. *Form Number:* CMS–10307 (OMB control number: 0938–1080); *Frequency:* On Occasion; *Affected Public:* State, Local, or Tribal Governments, Private Sector, Individuals; *Number of Respondents:* 282,657; *Total Annual Responses:* 1,125,558; *Total Annual Hours:* 93,797. (For policy questions regarding this collection contact Erik Gomez at 667–414–0682.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–10900 Filed 5–16–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Privacy Act of 1974; System of Records

AGENCY: Administration for Children and Families, Department of Health and Human Services.

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, the Department of Health and Human Services (HHS) is modifying an existing system of records maintained by the Administration for Children and Families (ACF), Office of Child Support Services (OCSS): System No. 09–80–0389, ''OCSE Data Center General Support System,'' being renamed ''OCSS Data Exchange Platform.''

DATES: This Notice is applicable May 17, 2024, subject to a 30-day period in which to comment on the new and revised routine uses, described below. Please submit any comments by June 17, 2024.

ADDRESSES: The public should address written comments by mail or email to: Anita Alford, Senior Official for Privacy, Administration for Children and Families, 330 C St. SW, Washington, DC 20201, or by email to *anita.alford@acf.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: General questions about these system of records should be submitted by mail or email to Venkata Kondapolu, Director, Division of Federal Systems, Office of Child Support Services, at 330 C St. SW—5th Floor, Washington, DC 20201, or *venkata.kondapolu@acf.hhs.gov,* or by phone at 202–260–4712.

SUPPLEMENTARY INFORMATION:

I. Explanation of Changes to System of Records 09–80–0381

In accordance with 5 U.S.C. 552a(e)(4) and (11), HHS is modifying an existing system of records maintained by ACF/OCSS: System No. 09–80–0389, being renamed ''OCSS Data Exchange Platform.'' The system of records covers records supporting State and Tribal child support programs, and the program's external stakeholders, which are exchanged electronically using a secure data exchange platform (the OCSS Data Exchange Platform, or any successor system) provided by OCSS. The data exchange platform facilitates electronic exchanges of information about individual participants in child support cases, between State child support agencies and other external partners such as employers, health plan administrators, financial institutions, and central authorities in foreign treaty countries or foreign countries that are the subject of a declaration under 42 U.S.C. 659a. The child support agencies and other external partners use the data exchange platform to electronically submit information to and receive information from each other, through OCSS.

The System of Records Notice (SORN) for system of records 09–80–0389 has been modified as follows:

- The system of records name has been changed to ''OCSS Data Exchange Platform'' to reflect the name change of the ''Office of Support Enforcement'' to the ''Office of Child Support Services'' and to provide a more meaningful name for the system of records.
- The System Manager(s) section has been revised to change the office name to Office of Child Support Services.
- The Purpose(s) section has been revised to describe the system as a data exchange platform, rather than as a ''gateway system,'' and one purpose, at the end of the section, has been expanded to include the use of the data exchange platform by foreign authorities to transmit case information associated with child support disbursements transmitted from a foreign authority to the United States through the Central Authority Payment (CAP) service.
- The Categories of Records section has been revised to make these changes to Category (4):
  - The phrase ''which includes'' has been changed to ''which may include.''
  - Under (4)(c), ''agency's case number'' had been changed to ''agency's case identifier.''

- The Record Source Categories section has been revised as follows:
  - The description of State child support agencies transmitting payment information to the CAP program has been modified to ''exchanging case-related information associated with child support disbursements transmitted to foreign authorities through the CAP service.''
  - An additional category has been added: ''[F]oreign authorities exchanging case-related information associated with child support disbursements transmitted to State child support agencies through the CAP service.''
- The Routine Uses section has been updated as follows:
  - The word ''enforcement'' has been removed from routine uses 1, 2, 4, and 6.
  - Routine use 11 has been revised to include disclosure of information involving residents of foreign treaty countries or foreign reciprocating countries to State child support programs for child support purposes.
- The Policies and Practices for Retention and Disposal of Records section has been revised to include General Records Schedule 5.2, items 010 and 020 as the applicable disposition authority.

Venkata Kondapolu,

Director, Division of Federal Systems, Office of Child Support Services, Administration for Children and Families, U.S. Department of Health and Human Services.

SYSTEM NAME AND NUMBER:

OCSS Data Exchange Platform, 09–80–0389.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Office of Child Support Services, Administration for Children and Families, 330 C St. SW, 5th Floor, Washington, DC 20201.

SYSTEM MANAGER(S):

Director, Division of Federal Systems, Office of Child Support Services, Administration for Children and Families, Department of Health and Human Services, 330 C St. SW, 5th Floor, Washington, DC 20201, *Venkata.Kondapolu@acf.hhs.gov,* 202–260–4712.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 652, 654, 654a, 654b, 659, 659a, 666, 669a.

PURPOSE(S) OF THE SYSTEM:

The purpose of the system of records is to cover records supporting State and Tribal child support programs, and the programs' external stakeholders, which are exchanged electronically using a secure data exchange platform provided by OCSS. The platform facilitates electronic exchanges of information about individual participants in child support cases, between State child support agencies and other external partners such as employers, health plan administrators, financial institutions, and central authorities in foreign treaty countries or foreign countries that are the subject of a declaration under 42 U.S.C. 659a. The child support agencies and other external partners use the data exchange platform to electronically submit information to and receive information from each other, through OCSS.

The platform supports, for example:

- The Electronic Income Withholding Order (e-IWO) program, which provides the means to electronically exchange income withholding order information between State child support agencies and employers.
- The Electronic National Medical Support Notice (e-NMSN) program, which allows State child support agencies, employers, and health plan administrators to electronically send and receive National Medical Support Notices used to enroll children in medical insurance plans pursuant to child support orders.
- The Federally Assisted State Transmitted (FAST) Levy program, which allows States and financial institutions to exchange information about levy actions through an electronic process.
- The Central Authority Payment (CAP) service, which allows States and foreign authorities to exchange details of child support disbursements transmitted between the United States and the authorized entity of the foreign treaty country or foreign country subject of a declaration under 42 U.S.C. 659a for distribution of the support payment by the foreign authority or the State child support agency in accordance with the terms of the order.

Multiple child support program partners utilize the platform to electronically send and receive information:

State child support agencies use the platform to transmit e-IWOs to employers and e-NMSNs to employers and health plan administrators. State child support agencies also use the platform to create levy actions for distribution to multiple financial institutions, and to transmit information about child support disbursements between U.S. States and foreign authorities through the CAP service.

Employers use the platform to respond to State child support agencies regarding e-IWOs and to provide information about health insurance coverage provided by the employer. Employers and health plan administrators use the platform to respond to State child support agencies regarding e-NMSNs.

Financial institutions use the platform to receive and respond to levy actions from multiple State child support agencies.

U.S. States and foreign authorities use the platform to transmit case information associated with child support disbursements transmitted between the United States and a foreign authority through the CAP service.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The records in the system of records are about custodial and noncustodial parents, legal guardians, and third-party caretakers who are participants in child support program cases and whose names and Social Security numbers (SSNs) are used to retrieve the records. Children's personal identifiers are not used to retrieve records in this system of records, so children are not subject individuals for purposes of this system of records.

CATEGORIES OF RECORDS IN THE SYSTEM:

The categories of records exchanged in the platform include:

1. Child support case information used to populate an e-IWO, which may include:

a. Name of State, Tribe, territory, or private individual entity issuing an e-IWO;

b. Order ID and Case ID;

c. Remittance ID;

d. Employer/income withholder name, address, Federal employer identification number (FEIN), telephone number, FAX number, email, or website;

e. Employee/obligor's name, Social Security number (SSN), date of birth;

f. Custodial parent's/obligee's name;

g. Child(ren)'s name(s) and date(s) of birth;

h. Income withholding amounts for current child support, past-due child support, current cash medical support, past-due cash medical support, current spousal support, past-due spousal support;

i. Child support State disbursement unit or Tribal order payee name and address;

j. Judge/issuing official's name, title, and signature; and

k. Employee/obligor termination date, last known telephone number, last

known address, new employer/income withholder's name and address.

2. Child support case information used to populate an e-NMSN, and medical insurance information included in e-NMSN responses from employers and health plan administrators, which may include:

a. Custodial parent/obligee's name and mailing address;

b. Substituted official/agency name and address (if custodial parent/obligee's address is left blank);

c. Name, telephone number, and mailing address of representative of child(ren);

d. Child(ren)'s name(s), gender, date of birth, and SSN;

e. Employee's name, SSN, and mailing address;

f. Plan administrator name, contact person, FAX number and telephone number;

g. Employer and/or employer representative name, FEIN, and telephone number;

h. Date of medical support termination, reason for termination, and child(ren) to be terminated from medical support;

i. Medical insurance provider name, group number, policy number, address;

j. Dental insurance provider name, group number, policy number, address;

k. Vision insurance provider name, group number, policy number, address;

l. Prescription drug insurance provider name, group number, policy number, address;

m. Mental health insurance provider name, group number, policy number, address;

n. Other insurance, specified by name, group number, policy number, address; and

o. Plan administrator name, title, telephone number and address.

3. Child support case information used to administer the FAST Levy program, which includes:

a. Requesting State agency name, address, and State Federal Information Processing Standard (FIPS) code;

b. Financial institution's name and FEIN;

c. Obligor's name, SSN, and date of birth;

d. Account number of account from which to withhold funds;

e. Withholding amount; and

f. Contact name, phone number, and email for point of contact in requesting State.

4. Child support case information used to administer the CAP service, which may include:

a. Obligor/non-custodial parent's name and SSN;

b. Foreign authority name, FIPS locator code, and foreign authority's child support case identifier;

c. U.S. State name and State child support agency's case identifier;

d. Amount and date of payment;

e. Medical support indicator; and

f. Employment termination indicator.

RECORD SOURCE CATEGORIES:

The sources of the information in the system of records include:

- State child support agencies initiating e-IWO, e-NMSN, and FAST Levy program transactions in domestic child support cases and exchanging case-related information associated with child support disbursements transmitted to foreign authorities through the CAP service.
- Employers or authorized third parties responding to e-IWOs and e-NMSNs.
- Health plan administrators responding to e-NMSNs.
- Financial institutions responding to FAST Levy requests.
- Foreign authorities exchanging case-related information associated with child support disbursements transmitted to State child support agencies through the CAP service.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to the disclosures authorized directly in the Privacy Act at 5 U.S.C. 552a(b)(1) and (b)(2) and (b)(4) through (b)(11), these routine uses specify circumstances under which the agency may disclose information from this system of records to a non-HHS officer or employee without the consent of the data subject. ACF will prohibit redisclosures, or may permit only certain redisclosures, as required or authorized by law. Each proposed disclosure or redisclosure of information permitted directly in the Privacy Act or under these routine uses will be evaluated to ensure that the disclosure or redisclosure is legally permissible.

Any information defined as ''return'' or ''return information'' under 26 U.S.C. 6103 (Internal Revenue Code) is not disclosed unless authorized by a statute, the Internal Revenue Service (IRS), or IRS regulations.

1. *Disclosure to Financial Institution to Collect Past-Due Support.*

Pursuant to 42 U.S.C. 652(l), information pertaining to an individual owing past-due child support may be disclosed to a financial institution doing business in two or more States to identify an individual who maintains an account at the institution for the purpose of collecting past-due support. Information pertaining to requests by the State child support agencies for the placement of a lien or levy of such accounts may also be disclosed.

2. *Disclosure of Financial Institution Information to State Child Support Agency for Assistance in Collecting Past-Due Support.*

Pursuant to 42 U.S.C. 652(l), the results of a comparison between information pertaining to an individual owing past-due child support and information provided by multistate financial institutions may be disclosed to a State child support agency for the purpose of assisting the State agency in collecting past-due support. Information pertaining to responses to requests by a State child support agency for the placement of a lien or levy of such accounts may also be disclosed.

3. *Disclosure to Employer to Enforce Child Support Obligations.*

Pursuant to 42 U.S.C. 666(b), information pertaining to an individual owing current or past-due child support may be disclosed to an employer for the purpose of collecting current or past-due support by way of an e-IWO.

4. *Disclosure of Employer Information to State Child Support Agency in Response to an e-IWO.*

Information pertaining to a response by an employer to an e-IWO issued by a State child support agency for the collection of child support may be disclosed to the State child support agency.

5. *Disclosure to Employer and Health Plan Administrator to Enforce Medical Support Obligations.*

Pursuant to 42 U.S.C. 666(a)(19), information pertaining to participants in a child support case may be disclosed to an employer or a health plan administrator for the purpose of enforcing medical support for a child by way of an e-NMSN.

6. *Disclosure of Employer and Health Plan Administrator Information to State Child Support Agency in Response to an e-NMSN.*

Information pertaining to a response by an employer or a health plan administrator to an e-NMSN issued by a State child support agency for the enforcement of medical support may be disclosed to the State child support agency.

7. *Disclosure to Department of Justice or in Proceedings.*

Records may be disclosed to the Department of Justice (DOJ) or to a court or other adjudicative body in litigation or other proceedings when HHS or any of its components, or any employee of HHS acting in the employee's official capacity, or any employee of HHS acting

in the employee's individual capacity where the DOJ or HHS has agreed to represent the employee, or the United States Government, is a party to the proceedings or has an interest in the proceedings and, by careful review, HHS determines that the records are both relevant and necessary to the proceedings.

8. *Disclosure to Congressional Office.*

Information may be disclosed to a congressional office from the record of an individual in response to a written inquiry from the congressional office made at the written request of the individual.

9. *Disclosure to Contractor to Perform Duties.*

Records may be disclosed to a contractor performing or working on a contract for HHS and who has a need to have access to the information in the performance of its duties or activities for HHS in accordance with law and with the contract.

10. *Disclosure in the Event of a Security Breach.*

a. Information may be disclosed to appropriate agencies, entities, and persons when (1) HHS suspects or has confirmed that there has been a breach of the system of records; (2) HHS has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, HHS (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with HHS's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

b. Information may be disclosed to another Federal agency or Federal entity, when HHS determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

11. *Disclosure to a Foreign Reciprocating Country, Foreign Treaty Country, and State Child Support Program for Child Support Purposes.*

Pursuant to 42 U.S.C. 652(n), 653(a)(2), 653(c)(5) and 659a(c)(2), child support case information involving residents of the United States and residents of foreign treaty countries or foreign countries that are the subject of a declaration under 42 U.S.C. 659a may be disclosed to the foreign authority and to State child support programs.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

The records are stored electronically.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by the parent's, guardian's or third-party caretaker's name or SSN.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Because the platform is not a source system but facilitates access to records from other systems which are the official sources of the records, the records are retained and disposed of in accordance with General Records Schedule 5.2 Transitory and Intermediary Records, Items 010 and 020 (DAA–GRS–2022–0009–0001 and DAA–GRS–2022–0009–0002), which provides these disposition periods:

- Item 010 Transitory records: Destroy when no longer needed for business use, or according to an agency predetermined time period or business rule.
- Item 020 Intermediary records: Destroy upon creation or update of the final record, or when no longer needed for business use, whichever is later.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

The platform leverages cloud service providers that maintain an authority to operate in accordance with applicable laws, rules, and policies, including Federal Risk and Authorization Management Program (FedRAMP) requirements. Specific administrative, technical, and physical controls are in place to ensure that the records collected, maintained, and transmitted using the platform are secure from unauthorized access. Access to the records within the system is restricted to authorized personnel who are advised of the confidentiality of the records and the civil and criminal penalties for misuse and who sign a nondisclosure oath to that effect. Agency personnel are provided privacy and security training before being granted access to the records and annually thereafter. Additional safeguards include protecting the facilities where records are stored or accessed with security guards, badges and cameras; limiting access to electronic databases to authorized users based on roles and either two-factor authentication or user ID and password (as appropriate); using a secured operating system protected by encryption, firewalls, and intrusion detection systems; reviewing security controls on a periodic basis; and using secure destruction methods prescribed in NIST SP 800–88 to dispose of eligible records. All safeguards conform to the HHS Information Security and Privacy Program, *https://www.hhs.gov/ocio/securityprivacy/index.html*.

RECORD ACCESS PROCEDURES:

To request access to a record about you in this system of records, submit a written access request to the System Manager identified in the ''System Manager'' section of this System of Records Notice (SORN). The request must reasonably describe the record sought and must include (for contact purposes and identity verification purposes) your full name, current address, telephone number and/or email address, date and place of birth, and signature, and (if needed by the agency) sufficient particulars contained in the records (such as, your SSN) to enable the System Manager to distinguish between records on subject individuals with the same name. In addition, to verify your identity, your signature must be notarized, or the request must include your written certification that you are the individual who you claim to be and that you understand that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense subject to a fine of up to $5,000. You may request that copies of the records be sent to you, or you may request an appointment to review the records in person (including with a person of your choosing, if you provide written authorization for agency personnel to discuss the records in that person's presence). You may also request an accounting of disclosures that have been made of records about you, if any.

CONTESTING RECORD PROCEDURES:

To request correction of a record about you in this system of records, submit a written amendment request to the System Manager identified in the ''System Manager'' section of this SORN. The request must contain the same information required for an access request and include verification of your identity in the same manner required for an access request. In addition, the request must reasonably identify the record and specify the information contested, the corrective action sought, and the reasons for requesting the correction; and should include supporting information to show how the

record is inaccurate, incomplete, untimely, or irrelevant.

NOTIFICATION PROCEDURES:

To find out if the system of records contains a record about you, submit a written notification request to the System Manager identified in the ''System Manager'' section of this SORN. The request must identify this system of records, contain the same information required for an access request, and include verification of your identity in the same manner required for an access request.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

87 FR 69026 (Nov. 17, 2022).

[FR Doc. 2024–10838 Filed 5–16–24; 8:45 am]

BILLING CODE 4184–42–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0150]

Revocation of Two Authorizations of Emergency Use of In Vitro Diagnostic Device for Detection and/or Diagnosis of COVID–19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorizations (EUAs) (the Authorizations) issued to Bio-Rad Laboratories Inc., for the Bio-Rad SARS–CoV–2 ddPCR Kit, and Fast Track Diagnostics Luxembourg S.á.r.l. (A Siemens Healthineers Company), for the FTD SARS–CoV–2. FDA revoked the Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by the Authorization holders. The revocations, which include an explanation of the reasons for each revocation, are reprinted at the end of this document.

DATES: The revocation of the Authorization for the Bio-Rad Laboratories Inc.'s Bio-Rad SARS–CoV–2 ddPCR Kit is effective as of March 27, 2024. The revocation of the Authorization for the Fast Track Diagnostics Luxembourg S.á.r.l.'s (A Siemens Healthineers Company), FTD SARS–CoV–2 is effective as of April 18, 2024.

ADDRESSES: Submit written requests for a single copy of the revocations to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the revocations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocations.

FOR FURTHER INFORMATION CONTACT: Kim Sapsford-Medintz, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3216, Silver Spring, MD 20993–0002, 301–796–0311 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, radiological, or nuclear agent or agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On May 1, 2020, FDA issued the Authorization to Bio-Rad Laboratories Inc., for the Bio-Rad SARS–CoV–2 ddPCR Kit, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on July 14, 2020 (85 FR 42409), as required by section 564(h)(1) of the FD&C Act.

On May 5, 2020, FDA issued the Authorization to Fast Track Diagnostics Luxembourg S.á.r.l. (a Siemens Healthineers Company) for the FTD SARS–CoV–2, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on July 14, 2020 (85 FR 42409), as required by section 564(h)(1) of the FD&C Act.

Subsequent updates to the Authorizations were made available on FDA's website. The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. Authorizations Revocation Requests

In a request received by FDA on March 16, 2024, Bio-Rad Laboratories Inc., requested the revocation of, and on March 27, 2024, FDA revoked, the Authorization for the Bio-Rad Laboratories Inc.'s Bio-Rad SARS–CoV–2 ddPCR Kit. Because Bio-Rad Laboratories Inc., notified FDA that they ceased United States distribution of the Bio-Rad SARS–CoV–2 ddPCR Kit and requested FDA revoke Bio-Rad Laboratories Inc.'s Bio-Rad SARS–CoV–2 ddPCR Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

In a request received by FDA on April 11, 2024, Fast Track Diagnostics Luxembourg S.á.r.l. (a Siemens Healthineers Company), requested the deregister of, and on April 18, 2024, FDA revoked, the Authorization for Fast Track Diagnostics Luxembourg S.á.r.l.'s FTD SARS–CoV–2. Because Fast Track Diagnostics Luxembourg S.á.r.l. notified FDA that they have ceased United States distribution of the FTD SARS–CoV–2 and requested FDA deregister the Fast Track Diagnostics Luxembourg S.á.r.l.'s FTD SARS–CoV–2, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

III. Electronic Access

An electronic version of this document and the full text of the revocations are available on the internet at *https://www.regulations.gov/.*

IV. The Revocations

Having concluded that the criteria for revocation of the Authorizations under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA of Bio-Rad Laboratories Inc.'s Bio-Rad SARS–CoV–2 ddPCR Kit, and Fast Track Diagnostics Luxembourg S.á.r.l.'s (a Siemens Healthineers Company) FTD SARS–CoV–2. The revocations in their entirety follow and provide an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164–01–P

U.S. FOOD & DRUG ADMINISTRATION

March 27, 2024

Elizabeth Platt, MLS(ASCP)^{CM}, CLS, ACRP-CP, CMDA, CQA, CSSGB, CMQ/OE, RAC
(Devices, Global, US)
VP, Regulatory & Clinical Affairs
Bio-Rad Laboratories Inc.
4000 Alfred Nobel Drive
Hercules, CA 94547
Re: Revocation of EUA200440

Dear Dr. Platt:

This letter is in response to the request from Bio-Rad Laboratories Inc., in a letter dated March 16, 2024, that the U.S. Food and Drug Administration (FDA revoke the EUA for the Bio-Rad SARS-CoV-2 ddPCR Kit issued on May 1, 2020, reissued on September 18, 2020, and amended on December 9, 2020, September 23, 2021, and March 15, 2022. Bio-Rad Laboratories Inc. indicated that they have ceased United States distribution of the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter there are no viable Bio-Rad SARS-CoV-2 ddPCR Kit reagents remaining in distribution in the United States.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Bio-Rad Laboratories Inc. has requested that FDA revoke the EUA for the Bio-Rad SARS-CoV-2 ddPCR Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200440 for the Bio-Rad SARS-CoV-2 ddPCR Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Bio-Rad SARS-CoV-2 ddPCR Kit is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

//s//

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

April 18, 2024

Oliver Jahnel
Regulatory Affairs Scientist, Molecular Diagnostics
Fast Track Diagnostics Luxembourg S.a.r.l.
A Siemens Healthineers Company
29, Rue Henri Koch
L-4354 Esch-sur-Alzette, Luxembourg
Re: Revocation of EUA200571

Dear Oliver Jahnel:

This letter is in response to the request from Fast Track Diagnostics Luxembourg S.á.r.l. (a Siemens Healthineers Company), in an email dated April 11, 2024, that the U.S. Food and Drug Administration (FDA) deregister the EUA for the FTD SARS-CoV-2 issued on May 5, 2020, amended on July 9, 2020, reissued on January 26, 2021, and amended on April 7, 2021, September 23, 2021, and January 19, 2022. Fast Track Diagnostics Luxembourg S.á.r.l. indicated that they have ceased United States distribution of the authorized product and requested that the EUA be deregistered. Communication with the company made clear that, based on their request, FDA would revoke the EUA. FDA understands that as of the date of this letter there are no viable FTD SARS-CoV-2 reagents remaining in distribution in the United States.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Fast Track Diagnostics Luxembourg S.á.r.l. has requested that FDA deregister the EUA for the FTD SARS-CoV-2, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200571 for the FTD SARS-CoV-2, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the FTD SARS-CoV-2 is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

//s//

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

Dated: May 14, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–10910 Filed 5–16–24; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances; Draft and Revised Draft Guidances 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 additional draft and revised draft product-specific guidances. The draft guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website. The draft

guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on the draft guidance by July 16, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

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

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2007–D–0369 for ''Product-Specific Guidances; Draft and Revised Draft Guidances for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''**THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION**.'' 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 the draft 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Christine Le, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4714, Silver Spring, MD 20993–0002, 301–796–2398, *PSG-Questions@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs.*

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. Under that process, draft guidances are posted on FDA's website and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final guidances or publishes revised draft guidances for comment. Guidances were last announced in the **Federal Register** on February 16, 2024 (89 FR 12354). This notice announces draft product-specific guidances, either new or revised, that are posted on FDA's website.

II. Drug Products for Which New Draft Product-Specific Guidances Are Available

FDA is announcing the availability of new draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active Ingredient(s)
Atorvastatin calcium
Baclofen
Bexagliflozin
Daprodustat
Elacestrant dihydrochloride
Gadopiclenol
Ganciclovir
Ganirelix acetate
Indomethacin
Lacosamide
Levodopa
Lidocaine hydrochloride
Liraglutide recombinant

TABLE 1—NEW DRAFT PRODUCT-—Continued
SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active Ingredient(s)
Lotilaner
Nalmefene hydrochloride
Omaveloxolone
Oxazepam
Pegcetacoplan
Perfluorohexyloctane
Pirtobrutinib
Rezafungin acetate
Sodium oxybate
Sparsentan
Tasimelteon
Tobramycin
Zavegepant hydrochloride

III. Drug Products for Which Revised Draft Product-Specific Guidances Are Available

FDA is announcing the availability of revised draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active Ingredient(s)
Benzoyl peroxide; Erythromycin (multiple reference listed drugs)
Fluticasone furoate
Fluticasone furoate; Vilanterol trifenatate
Nitrofurantoin
Tretinoin

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to *https://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

FDA tentatively concludes that these draft guidances contain no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov*.

Dated: May 14, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–10896 Filed 5–16–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Proposed Purchased/Referred Care Delivery Area Re-Designation for the Pokagon Band of Potawatomi Indians of Michigan and Indiana

AGENCY: Indian Health Service, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This Notice advises the public that the Indian Health Service (IHS) proposes to expand the geographic boundaries of the Purchased/Referred Care Delivery Area (PRCDA) for the Pokagon Band of Potawatomi Indians of Michigan and Indiana to include the counties of Kalamazoo, Kent, and Ottawa in the State of Michigan. The sole purpose of this expansion would be to authorize additional Pokagon Band of Potawatomi Indians of Michigan and Indiana citizens and other PRC-eligible individuals to receive PRC services.

DATES: Comments must be submitted by June 17, 2024.

ADDRESSES: Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of four 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: Carl Mitchell, Director, Division of Regulatory and Policy Coordination, Indian Health Service, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, Maryland 20857.

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 above address.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to the address above.

If you intend to deliver your comments to the Rockville address, please call telephone number (301) 443–1116 in advance to schedule your arrival with a staff member.

FOR FURTHER INFORMATION CONTACT: CAPT John Rael, Director, Office of Resource Access and Partnerships, Indian Health Service, 5600 Fishers Lane, Mail Stop: 10E85C, Rockville, Maryland 20857. Telephone (301) 443–0969 (This is not a toll free number).

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.

Background: The IHS provides services under regulation in effect as of September 15, 1987, and republished at 42 CFR part 136, subparts A–C. Subpart C defines a Contract Health Service Delivery Area (CHSDA), now referred to as PRCDA, as the geographic area within which PRC will be made available by the IHS to members of an identified Indian community who reside in the PRCDA. Residence within a PRCDA by a person who is within the scope of the Indian health program, as set forth in 42 CFR 136.12, creates no legal entitlement to PRC but only potential eligibility for services. Services needed, but not available at an IHS/Tribal facility, are provided under the PRC program depending on the availability of funds, the relative medical priority of the services to be provided, and the actual availability and accessibility of alternate resources in accordance with the regulations.

The regulations at 42 CFR part 136, subpart C provide that, unless otherwise designated, a PRCDA shall consist of a county which includes all or part of a reservation and any county or counties which have a common boundary with the reservation. 42 CFR 136.22(a)(6). The regulations also provide that after consultation with the Tribal governing body or bodies on those reservations included within the PRCDA, the Secretary may, from time to time, re-designate areas within the United States for inclusion in or exclusion from a PRCDA. 42 CFR 136.22(b).

The regulations require that certain criteria must be considered before any

re-designation is made. The criteria are as follows:

(1) The number of Indians residing in the area proposed to be so included or excluded;

(2) Whether the Tribal governing body has determined that Indians residing in the area near the reservation are socially and economically affiliated with the Tribe;

(3) The geographic proximity to the reservation of the area whose inclusion or exclusion is being considered; and

(4) The level of funding which would be available for the provision of PRC. Additionally, the regulations require that any re-designation of a PRCDA must be made in accordance with the procedures of the Administrative Procedure Act (5 U.S.C. 553). 42 CFR 136.22(c). In compliance with this requirement, the IHS is publishing this Notice and requesting public comments.

The Pokagon Band of Potawatomi Indians of Michigan and Indiana (Pokagon Band, or Tribe) is located in Dowagiac, Michigan, and operates their PRC program as a Tribal Health Program. The IHS established the Pokagon Band's current PRCDA consistent with the language of the Act of September 21, 1994, restoring Federal recognition to the Pokagon Band. Public Law 103–323 (108 Stat. 2152); *see also* 72 FR 34262 (June 21, 2007). Although the IHS has historically established PRCDAs in accordance with Congressional intent, the IHS has also preserved regulatory flexibility to re-designate areas as appropriate for inclusion in or exclusion from a PRCDA under PRC regulations. *See* 81 FR 20388 (April 7, 2016).

The current PRCDA for the Pokagon Band of Potawatomi Indians of Michigan and Indiana currently consists of 10 counties in Southwestern Michigan and Northwestern Indiana. *See* 72 FR 34262 (June 21, 2007). These counties are Allegan, Berrien, Cass, and Van Buren Counties in Michigan; and Elkhart, Kosciusko, La Porte, Marshall, St. Joseph, and Starke Counties in Indiana. Pokagon Band of Potawatomi Indians of Michigan and Indiana citizens residing outside of the PRCDA are eligible for direct care services; however, they are not eligible for Purchased/Referred Care (PRC) services.

The Pokagon Band estimates that approximately 537 Pokagon citizens reside in Kalamazoo, Kent, and Ottawa Counties in Michigan and would become PRC eligible through the proposed re-designation and expansion of the Tribe's PRCDA. The Pokagon Band states that these citizens, ''by virtue of their citizenship with the Pokagon Band are socially and economically affiliated with the Pokagon Band and belong to the Pokagon Band community served by the [Health] Center . . .'' The Tribe also considers certain other PRC-eligible individuals to be socially and economically affiliated with the Pokagon Band and to belong to the Pokagon Band community, including non-Indian women pregnant with a Pokagon Band citizen's child, and children of Pokagon Band citizens as detailed in the Tribe's PRCDA re-designation request. The Pokagon Band would like to recognize these persons as eligible for PRC services. The IHS confirmed that there are Pokagon Band citizens residing in each of the proposed expansion counties. Accordingly, the IHS proposes to expand the PRCDA of the Pokagon Band of Potawatomi Indians of Michigan and Indiana to include the Michigan counties of Kalamazoo, Kent, and Ottawa.

If the Pokagon Band's PRCDA re-designation and expansion is finalized as proposed, the Tribe's expanded PRCDA would overlap the existing PRCDAs of three other Tribes: the Nottawaseppi Band of Huron Potawatomi (Kalamazoo, Kent, and Ottawa Counties); the Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians of Michigan (Kalamazoo, Kent, and Ottawa Counties); and Little River Band of Ottawa Indians (Kent and Ottawa Counties). The IHS has consulted with each of the overlapping Tribes regarding the proposed expansion of the Pokagon Band's PRCDA, and none of the overlapping Tribes has expressed a current concern regarding the proposed re-designation and expansion.

Under 42 CFR 136.23, those otherwise eligible Indians who do not reside on a reservation, but reside within a PRCDA, must be either members of the Tribe or other IHS beneficiaries who maintain close economic and social ties with the Tribe. In this case, applying the aforementioned PRCDA re-designation criteria required by operative regulations codified at 42 CFR part 136, subpart C, the following findings are made:

1. By expanding the PRCDA to include Kalamazoo, Kent, and Ottawa Counties in Michigan, the Pokagon Band of Potawatomi Indians of Michigan and Indiana's PRC eligible population will increase by an estimated 537 Tribal citizens.

2. The IHS finds that the Tribal citizens and other PRC-eligible individuals within the expanded PRCDA are socially and economically affiliated with the Pokagon Band based on a Tribal resolution in which the Pokagon Band Tribal Council identified its intent to expand the PRCDA to include Kalamazoo, Kent, and Ottawa Counties in Michigan, and stated that the Tribal citizens and certain other individuals residing in such areas are socially and economically affiliated with the Pokagon Band.

3. The expanded PRCDA counties form a contiguous area with the existing PRCDA, and Pokagon Band citizens reside in each of the counties proposed for inclusion in the expanded PRCDA. For these reasons, the IHS has determined the additional counties proposed for inclusion herein to be geographically proximate, meaning ''on or near,'' to the existing PRCDA.

4. The Pokagon Band has indicated that its PRC program can continue providing the same level of care to the PRC-eligible population if the PRCDA is expanded as proposed, without requiring additional funding or reduction of the current medical priority level.

This Notice does not contain reporting or recordkeeping requirements subject to prior approval by the Office of Management and Budget under the Paperwork Reduction Act of 1980.

Roselyn Tso,

Director, Indian Health Service.

[FR Doc. 2024–10845 Filed 5–16–24; 8:45 am]

BILLING CODE 4166–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Initial Review Group; Transition to Independence Study Section (I), June 5, 2024, 8 a.m. to June 6, 2024, 1 p.m., Cambria Hotel Rockville, 1 Helen Heneghan Way, Rockville, Maryland 20850 which was published in the **Federal Register** on May 10, 2024, FR Doc 2024–10229, 89 FR 40496. This notice is being amended to change the meeting format from in-person to virtual and the meeting time from 8 a.m. to 1 p.m. to 11 a.m. to 4 p.m. The meeting will now be held virtually, June 5, 2024, 11 a.m. to June 6, 2024, 4 p.m., National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W238, Rockville, Maryland 20850. The meeting is closed to the public.

Dated: May 14, 2024.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–10873 Filed 5–16–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 1009 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 Heart, Lung, and Blood Institute Special Emphasis Panel; Clinical Trials SEP (R61).

Date: June 27, 2024.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Zhihong Shan, Ph.D., MD, Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 205–J, Bethesda, MD 20892, (301) 827–7085, *zhihong.shan@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 14, 2024.

Patricia B. Hansberger,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–10874 Filed 5–16–24; 8:45 am]

BILLING CODE 4140–01–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 1009 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; CARE–T1D Consortium.

Date: June 20, 2024.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NIDDK, Democracy II, Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Lan Tian, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, 6707 Democracy Boulevard, Bethesda, MD 20892, Bethesda, MD 20892–2542, *tianl@niddk.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)

Dated: May 14, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–10886 Filed 5–16–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Notice Regarding the Uyghur Forced Labor Prevention Act Entity List

AGENCY: Department of Homeland Security.

ACTION: Notice.

SUMMARY: The U.S. Department of Homeland Security (DHS), as the Chair of the Forced Labor Enforcement Task Force (FLETF), announces the publication and availability of the updated Uyghur Forced Labor Prevention Act (UFLPA) Entity List, a consolidated register of the four lists required to be developed and maintained pursuant to section 2(d)(2)(B) of the UFLPA, on the DHS UFLPA website. The updated UFLPA Entity List is also published as an appendix to this notice. This update adds twenty-six entities to the section 2(d)(2)(B)(v) list of the UFLPA, which identifies facilities and entities that source material from Xinjiang Uyghur Autonomous Region or from persons working with the government of Xinjiang or the Xinjiang Production and Construction Corps for purposes of the ''poverty alleviation'' program or the ''pairing-assistance'' program or any other government labor scheme that uses forced labor. Details related to the process for revising the UFLPA Entity List are included in this **Federal Register** notice.

DATES: This notice announces the publication and availability of the UFLPA Entity List updated as of May 17, 2024, included as an appendix to this notice.

ADDRESSES: Persons seeking additional information on the UFLPA Entity List should email the FLETF at *FLETF.UFLPA.EntityList@hq.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: LeRoy Potts, Director, Entity List Office, Trade and Economic Security, Office of Strategy, Policy, and Plans, DHS. Phone: (202) 891–2331, Email: *FLETF.UFLPA.EntityList@hq.dhs.gov.*

SUPPLEMENTARY INFORMATION: The U.S. Department of Homeland Security (DHS), on behalf of the Forced Labor Enforcement Task Force (FLETF), is announcing the publication of the updated UFLPA Entity List, a consolidated register of the four lists required to be developed and maintained pursuant to section 2(d)(2)(B) of the Uyghur Forced Labor Prevention Act (Pub. L. 117–78) (UFLPA), to *https://www.dhs.gov/uflpa-entity-list.* The UFLPA Entity List is available as an appendix to this notice. This update adds twenty-six entities to the section 2(d)(2)(B)(v) list of the UFLPA, which identifies facilities and entities that source material from Xinjiang Uyghur Autonomous Region or from persons working with the government of Xinjiang or the Xinjiang Production and Construction Corps for purposes of the ''poverty alleviation'' program or the ''pairing-assistance'' program or any other government labor scheme that uses forced labor. Future

revisions to the UFLPA Entity List, which may include additions, removals or technical corrections, will be published to *https://www.dhs.gov/uflpa-entitylist* and in the appendices of future **Federal Register** notices. *See* Appendix 1.

Beginning on June 21, 2022, the UFLPA requires the Commissioner of U.S. Customs and Border Protection to apply a rebuttable presumption that goods mined, produced, or manufactured by entities on the UFLPA Entity List are made with forced labor, and therefore, prohibited from importation into the United States under 19 U.S.C. 1307. *See* section 3(a) of the UFLPA. As the FLETF revises the UFLPA Entity List, including by making additions, removals, or technical corrections, DHS, on its behalf, will post such revisions to the DHS UFLPA website (*https://www.dhs.gov/uflpa-entity-list*) and also publish the revised UFLPA Entity List as an appendix to a **Federal Register** notice.

Background

A. The Forced Labor Enforcement Task Force

Section 741 of the United States-Mexico-Canada Agreement Implementation Act established the FLETF to monitor United States enforcement of the prohibition under section 307 of the Tariff Act of 1930, as amended (19 U.S.C. 1307). *See* 19 U.S.C. 4681. Pursuant to DHS Delegation Order No. 23034, the DHS Under Secretary for Strategy, Policy, and Plans serves as Chair of the FLETF, an interagency task force that includes the Department of Homeland Security, the Office of the U.S. Trade Representative, and the Departments of Labor, State, Justice, the Treasury, and Commerce (member agencies).[1] *See* 19 U.S.C. 4681; Executive Order 13923 (May 15, 2020). In addition, the FLETF includes six observer agencies: the Departments of Energy and Agriculture, the U.S. Agency for International Development, the National Security Council, U.S. Customs and Border Protection, and U.S. Immigration and Customs Enforcement Homeland Security Investigations.

[1] The U.S. Department of Homeland Security, as the FLETF Chair, has the authority to invite representatives from other executive departments and agencies, as appropriate. *See* Executive Order 13923 (May 15, 2020). The U.S. Department of Commerce is a member of the FLETF as invited by the Chair.

B. The Uyghur Forced Labor Prevention Act: Preventing Goods Made With Forced Labor in the People's Republic of China From Being Imported Into the United States

The UFLPA requires, among other things, that the FLETF, in consultation with the Secretary of Commerce and the Director of National Intelligence, develop a strategy (UFLPA section 2(c)) for supporting enforcement of section 307 of the Tariff Act of 1930, to prevent the importation into the United States of goods, wares, articles, and merchandise mined, produced, or manufactured wholly or in part with forced labor in the People's Republic of China. As required by the UFLPA, the *Strategy to Prevent the Importation of Goods Mined, Produced, or Manufactured with Forced Labor in the People's Republic of China,* which was published on the DHS website on June 17, 2022 (*see https://www.dhs.gov/uflpa-strategy*), includes the initial UFLPA Entity List, a consolidated register of the four lists required to be developed and maintained pursuant to the UFLPA. *See* UFLPA section 2(d)(2)(B).

C. UFLPA Entity List

The UFLPA Entity List addresses distinct requirements set forth in clauses (i), (ii), (iv), and (v) of section 2(d)(2)(B) of the UFLPA that the FLETF identify and publish the following four lists:

(1) a list of entities in the Xinjiang Uyghur Autonomous Region that mine, produce, or manufacture wholly or in part any goods, wares, articles, and merchandise with forced labor;

(2) a list of entities working with the government of the Xinjiang Uyghur Autonomous Region to recruit, transport, transfer, harbor or receive forced labor or Uyghurs, Kazakhs, Kyrgyz, or members of other persecuted groups out of the Xinjiang Uyghur Autonomous Region;

(3) a list of entities that exported products made by entities in lists 1 and 2 from the People's Republic of China into the United States; and

(4) a list of facilities and entities, including the Xinjiang Production and Construction Corps, that source material from the Xinjiang Uyghur Autonomous Region or from persons working with the government of Xinjiang or the Xinjiang Production and Construction Corps for purposes of the ''poverty alleviation'' program or the ''pairing-assistance'' program or any other government-labor scheme that uses forced labor.

The UFLPA Entity List is a consolidated register of the above four lists. In accordance with section 3(e) of the UFLPA, effective June 21, 2022, entities on the UFLPA Entity List (listed entities) are subject to the UFLPA's rebuttable presumption that products they produce, wholly or in part, are prohibited from entry into the United States under 19 U.S.C. 1307. The UFLPA Entity List is described in Appendix 1 to this notice. The UFLPA Entity List should not be interpreted as an exhaustive list of entities engaged in the practices described in clauses (i), (ii), (iv), or (v) of section 2(d)(2)(B) of the UFLPA.

Revisions to the UFLPA Entity List, including all additions, removals, and technical corrections, will be published on the DHS UFLPA website (*https://www.dhs.gov/uflpa-entity-list*) and as an Appendix to a notice that will be published in the **Federal Register**. *See* Appendix 1. The FLETF will consider future additions to, or removals from, the UFLPA Entity List based on criteria described in clauses (i), (ii), (iv), or (v) of section 2(d)(2)(B) of the UFLPA. Any FLETF member agency may submit a recommendation(s) to add, remove or make technical corrections to an entry on the UFLPA Entity List. FLETF member agencies will review and vote on revisions to the UFLPA Entity List accordingly.

Additions to the Entity List

The FLETF will consider future additions to the UFLPA Entity List based on the criteria described in clauses (i), (ii), (iv), or (v) of section 2(d)(2)(B) of the UFLPA. Any FLETF member agency may submit a recommendation to the FLETF Chair to add an entity to the UFLPA Entity List. Following review of the recommendation by the FLETF member agencies, the decision to add an entity to the UFLPA Entity List will be made by majority vote of the FLETF member agencies.

Requests for Removal From the Entity List

Any listed entity may submit a request for removal (removal request) from the UFLPA Entity List along with supporting information to the FLETF Chair at *FLETF.UFLPA.EntityList@hq.dhs.gov.* In the removal request, the entity (or its designated representative) should provide information that demonstrates that the entity no longer meets or does not meet the criteria described in the applicable clause ((i), (ii), (iv), or (v)) of section 2(d)(2)(B) of the UFLPA. The FLETF Chair will refer all such removal requests and supporting information to FLETF member agencies. Upon receipt of the

removal request, the FLETF Chair or the Chair's designated representative may contact the entity on behalf of the FLETF regarding questions on the removal request and may request additional information. Following review of the removal request by the FLETF member agencies, the decision to remove an entity from the UFLPA Entity List will be made by majority vote of the FLETF member agencies.

Listed entities may request a meeting with the FLETF after submitting a removal request in writing to the FLETF Chair at *FLETF.UFLPA.EntityList@hq.dhs.gov.* Following its review of a removal request, the FLETF may accept the meeting request at the conclusion of the review period and, if accepted, will hold the meeting prior to voting on the entity's removal request. The FLETF Chair will advise the entity in writing of the FLETF's decision on its removal request. While the FLETF's decision on a removal request is not appealable, the FLETF will consider new removal requests if accompanied by new information.

Robert Silvers,

Under Secretary, Office of Strategy, Policy, and Plans, U.S. Department of Homeland Security.

Appendix 1

This notice supersedes the UFLPA Entity List published in the **Federal Register** on December 11, 2023 (88 FR 85899). The UFLPA Entity List as of May 17, 2024 is available in this appendix and is published on *https://www.dhs.gov/uflpa-entity-list.* This update adds twenty-six entities to the section 2(d)(2)(B)(v) list of the UFLPA, which identifies facilities and entities that source material from the Xinjiang Uyghur Autonomous Region or from persons working with the government of Xinjiang or the Xinjiang Production and Construction Corps for purposes of the ''poverty alleviation'' program or the ''pairing-assistance'' program or any other government labor scheme that uses forced labor. The twenty-six entities listed are cotton traders or warehouse facilities that the United States government has reasonable cause to believe, based on specific and articulable information, source cotton from the Xinjiang Uyghur Autonomous Region. That specific and articulable information includes an online wholesale platform that, as recently as April of 2024, marketed cotton sourced from the Xinjiang Uyghur Autonomous Region for sale by twenty-one of the listed entities, as well as corporate documents, websites, or media reports indicating that five other listed entities source cotton from the Xinjiang Uyghur Autonomous Region. Given information that indicates all twenty-six companies source cotton from the Xinjiang Uyghur Autonomous Region, the FLETF determined that the activities of the entities satisfy the criteria for addition to the section 2(d)(2)(B)(v) list of the UFLPA.

- Binzhou Chinatex Yintai Industrial Co., Ltd.,
- China Cotton Group Henan Logistics Park Co., Ltd., Xinye Branch,
- China Cotton Group Nangong Hongtai Cotton Co., Ltd.,
- China Cotton Group Shandong Logistics Park Co., Ltd.,
- China Cotton Group Xinjiang Cotton Co.,
- Fujian Minlong Warehousing Co., Ltd.,
- Henan Yumian Group Industrial Co., Ltd.,
- Henan Yumian Logistics Co., Ltd. (formerly known as 841 Cotton Transfer Warehouse),
- Hengshui Cotton and Linen Corporation Reserve Library,
- Heze Cotton and Linen Co., Ltd.,
- Heze Cotton and Linen Economic and Trade Development Corporation (also known as Heze Cotton and Linen Trading Development General Company),
- Huangmei Xiaochi Yinfeng Cotton (formerly known as Hubei Provincial Cotton Corporation's Xiaochi Transfer Reserve),
- Hubei Jingtian Cotton Industry Group Co., Ltd.,
- Hubei Qirun Investment Development Co., Ltd.,
- Hubei Yinfeng Cotton Co., Ltd.,
- Hubei Yinfeng Warehousing and Logistics Co., Ltd.,
- Jiangsu Yinhai Nongjiale Storage Co., Ltd.,
- Jiangsu Yinlong Warehousing and Logistics Co., Ltd.,
- Jiangyin Lianyun Co. Ltd. (also known as Jiangyin Intermodal Transport Co. and Jiangyin United Transport Co.),
- Jiangyin Xiefeng Cotton and Linen Co., Ltd.,
- Juye Cotton and Linen Station of the Heze Cotton and Linen Corporation,
- Lanxi Huachu Logistics Co., Ltd.,
- Linxi County Fangpei Cotton Buying and Selling Co., Ltd.,
- Nanyang Hongmian Logistics Co., Ltd. (also known as Nanyang Red Cotton Logistics Co., Ltd.),
- Wugang Zhongchang Logistics Co., Ltd.,
- Xinjiang Yinlong Agricultural International Cooperation Co.

No technical corrections or removals are being made to the UFLPA Entity List at this time.

The UFLPA Entity List is a consolidated register of the four lists that are required to be developed and maintained pursuant to section 2(d)(2)(B) of the UFLPA. Sixty-five entities [2] that meet the criteria set forth in the four required lists (*see* sections 2(d)(2)(B)(i), (ii), (iv), and (v) of the UFLPA) are specified on the UFLPA Entity List.

UFLPA Entity List May 17, 2024

UFLPA Section 2(d)(2)(B)(i) A List of Entities in Xinjiang That Mine, Produce, or Manufacture Wholly or in Part any Goods, Wares, Articles, and Merchandise With Forced Labor

Baoding LYSZD Trade and Business Co., Ltd.

Changji Esquel Textile Co. Ltd. (and one alias: Changji Yida Textile)

Hetian Haolin Hair Accessories Co. Ltd. (and two aliases: Hotan Haolin Hair Accessories; and Hollin Hair Accessories)

Hetian Taida Apparel Co., Ltd (and one alias: Hetian TEDA Garment)

Hoshine Silicon Industry (Shanshan) Co., Ltd (including one alias: Hesheng Silicon Industry (Shanshan) Co.) and subsidiaries

Xinjiang Daqo New Energy, Co. Ltd (including three aliases: Xinjiang Great New Energy Co., Ltd.; Xinjiang Daxin Energy Co., Ltd.; and Xinjiang Daqin Energy Co., Ltd.)

Xinjiang East Hope Nonferrous Metals Co. Ltd. (including one alias: Xinjiang Nonferrous)

Xinjiang GCL New Energy Material Technology, Co. Ltd (including one alias: Xinjiang GCL New Energy Materials Technology Co.)

Xinjiang Junggar Cotton and Linen Co., Ltd.

Xinjiang Production and Construction Corps (including three aliases: XPCC; Xinjiang Corps; and Bingtuan) and its subordinate and affiliated entities

[2] Since the most recent update published on December 11, 2023, the FLETF has updated the method it uses to count the number of entities. Beginning with this update, the FLETF now individually counts all named subsidiaries. This change increases the total count by nine, to account for subsidiaries identified in the June 12, 2023 (**Federal Register**:: Notice Regarding the Uyghur Forced Labor Prevention Act Entity List) and August 2, 2023 (**Federal Register**:: Notice Regarding the Uyghur Forced Labor Prevention Act Entity List).

UFLPA Section 2(d)(2)(B)(ii) A List of Entities Working With the Government of Xinjiang To Recruit, Transport, Transfer, Harbor or Receive Forced Labor or Uyghurs, Kazakhs, Kyrgyz, or Members of Other Persecuted Groups out of Xinjiang

Aksu Huafu Textiles Co. (including two aliases: Akesu Huafu and Aksu Huafu Dyed Melange Yarn)
Anhui Xinya New Materials Co., Ltd. (formerly known as Chaohu Youngor Color Spinning Technology Co., Ltd.; and Chaohu Xinya Color Spinning Technology Co., Ltd.)
Camel Group Co., Ltd.
COFCO Sugar Holdings Co., Ltd.
Geehy Semiconductor Co., Ltd.
Hefei Bitland Information Technology Co., Ltd. (including three aliases: Anhui Hefei Baolongda Information Technology; Hefei Baolongda Information Technology Co., Ltd.; and Hefei Bitland Optoelectronic Technology Co., Ltd.)
Hefei Meiling Co. Ltd. (including one alias: Hefei Meiling Group Holdings Limited).
KTK Group (including three aliases: Jiangsu Jinchuang Group; Jiangsu Jinchuang Holding Group; and KTK Holding)
Lop County Hair Product Industrial Park
Lop County Meixin Hair Products Co., Ltd.
Nanjing Synergy Textiles Co., Ltd. (including two aliases: Nanjing Xinyi Cotton Textile Printing and Dyeing; and Nanjing Xinyi Cotton Textile).
Ninestar Corporation
No. 4 Vocation Skills Education Training Center (VSETC)
Sichuan Jingweida Technology Group Co., Ltd. (also known as Sichuan Mianyang Jingweida Technology Co., Ltd. and JWD Technology; and formerly known as Mianyang High-tech Zone Jingweida Technology Co., Ltd.)
Tanyuan Technology Co. Ltd. (including five aliases: Carbon Yuan Technology; Changzhou Carbon Yuan Technology Development; Carbon Element Technology; Jiangsu Carbon Element Technology; and Tanyuan Technology Development).
Xinjiang Production and Construction Corps (XPCC) and its subordinate and affiliated entities
Xinjiang Tianmian Foundation Textile Co., Ltd.
Xinjiang Tianshan Wool Textile Co. Ltd.
Xinjiang Zhongtai Chemical Co. Ltd.
Xinjiang Zhongtai Group Co. Ltd
Zhuhai Apex Microelectronics Co., Ltd.
Zhuhai G&G Digital Technology Co., Ltd.
Zhuhai Ninestar Information Technology Co. Ltd.
Zhuhai Ninestar Management Co., Ltd.
Zhuhai Pantum Electronics Co. Ltd.
Zhuhai Pu-Tech Industrial Co., Ltd.
Zhuhai Seine Printing Technology Co., Ltd.

UFLPA Section 2(d)(2)(B)(iv) A List of Entities That Exported Products Described in Clause (iii) From the People's Republic of China Into the United States

Entities identified in sections (i) and (ii) above may serve as both manufacturers and exporters. The FLETF has not identified additional exporters at this time but will continue to investigate and gather information about additional entities that meet the specified criteria.

UFLPA Section 2(d)(2)(B)(v) A List of Facilities and Entities, Including the Xinjiang Production and Construction Corps, That Source Material From Xinjiang or From Persons Working With the Government of Xinjiang or the Xinjiang Production and Construction Corps for Purposes of the ''Poverty Alleviation'' Program or the ''Pairing-Assistance'' Program or any Other Government Labor Scheme That Uses Forced Labor

Baoding LYSZD Trade and Business Co., Ltd.
Binzhou Chinatex Yintai Industrial Co., Ltd.
Chenguang Biotech Group Co., Ltd.
Chenguang Biotechnology Group Yanqi Co. Ltd.
China Cotton Group Henan Logistics Park Co., Ltd., Xinye Branch
China Cotton Group Nangong Hongtai Cotton Co., Ltd.
China Cotton Group Shandong Logistics Park Co., Ltd.
China Cotton Group Xinjiang Cotton Co.
Fujian Minlong Warehousing Co., Ltd.
Hefei Bitland Information Technology Co. Ltd.
Henan Yumian Group Industrial Co., Ltd.
Henan Yumian Logistics Co., Ltd. (formerly known as 841 Cotton Transfer Warehouse)
Hengshui Cotton and Linen Corporation Reserve Library
Hetian Haolin Hair Accessories Co. Ltd.
Hetian Taida Apparel Co., Ltd.
Heze Cotton and Linen Co., Ltd.
Heze Cotton and Linen Economic and Trade Development Corporation (also known as Heze Cotton and Linen Trading Development General Company)
Hoshine Silicon Industry (Shanshan) Co., Ltd., and Subsidiaries
Huangmei Xiaochi Yinfeng Cotton (formerly known as Hubei Provincial Cotton Corporation's Xiaochi Transfer Reserve)
Hubei Jingtian Cotton Industry Group Co., Ltd.
Hubei Qirun Investment Development Co., Ltd.
Hubei Yinfeng Cotton Co., Ltd.
Hubei Yinfeng Warehousing and Logistics Co., Ltd.
Jiangsu Yinhai Nongjiale Storage Co., Ltd.
Jiangsu Yinlong Warehousing and Logistics Co., Ltd.
Jiangyin Lianyun Co. Ltd. (also known as Jiangyin Intermodal Transport Co. and Jiangyin United Transport Co.)
Jiangyin Xiefeng Cotton and Linen Co., Ltd.
Juye Cotton and Linen Station of the Heze Cotton and Linen Corporation
Lanxi Huachu Logistics Co., Ltd.
Linxi County Fangpei Cotton Buying and Selling Co., Ltd.
Lop County Hair Product Industrial Park
Lop County Meixin Hair Products Co., Ltd.
Nanyang Hongmian Logistics Co., Ltd. (also known as Nanyang Red Cotton Logistics Co., Ltd.)
No. 4 Vocation Skills Education Training Center (VSETC)
Wugang Zhongchang Logistics Co., Ltd.
Xinjiang Junggar Cotton and Linen Co., Ltd.
Xinjiang Production and Construction Corps (XPCC) and its subordinate and affiliated entities
Xinjiang Yinlong Agricultural International Cooperation Co.
Yili Zhuowan Garment Manufacturing Co., Ltd.

[FR Doc. 2024–10544 Filed 5–16–24; 8:45 am]
BILLING CODE 9110–9M–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2024–0014]

Notice of Meeting; Homeland Security Academic Partnership Council

AGENCY: Office of Partnership and Engagement (OPE), U.S. Department of Homeland Security (DHS).

ACTION: Notice of open Federal advisory committee meeting.

SUMMARY: OPE is publishing this notice that the Homeland Security Academic Partnership Council (HSAPC) will meet virtually on Monday, June 3, 2024 from 2 p.m. EST to 3:30 p.m. EST. This meeting will be open to the public.

DATES: The meeting will take place from 2 p.m. EST to 3:30 p.m. EST on June 3, 2024. Please note that the meeting may end early if the HSAPC completes its business.

ADDRESSES: The HSAPC meeting will be held via Zoom. Members of the public

interested in participating may do so by following the process outlined below. The public will remain in listen-only mode except during the public comment session. Members of the public may register to participate in this Council meeting via Zoom under the following procedures. Each individual must provide their full legal name and email address no later than 5 p.m. EST on Friday, May 31, 2024 to Patrese Roberts via email at *HSAPC@HQ.DHS.GOV* or via phone at 202–987–9802. Members of the public who have registered to participate will be provided the Zoom link, a copy of the agenda, and the two draft subcommittee reports prior to the start of the meeting. Written comments must be submitted no later than 5 p.m. EST on Friday, May 31, 2024. Comments must be identified by Docket No. DHS–2024–0014 and may be submitted by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: HSAPC@hq.dhs.gov.* Include Docket No. DHS–2024–0014 in the subject line of the message.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and ''DHS–2024–0014,'' the docket number for your comments. Comments received will be posted without alteration at *http://www.regulations.gov* including any personal information provided. You may wish to review the Privacy and Security Notice found via a link on the homepage of *www.regulations.gov.*

Docket: For access to the docket to read comments received by the Council, go to *http://www.regulations.gov,* search ''DHS–2024–0014,'' ''Open Docket Folder'' to view the comments.

FOR FURTHER INFORMATION CONTACT: Patrese Roberts, Alternate Designated Federal Officer of the Homeland Security Academic Partnership Council, U.S. Department of Homeland Security at *HSAPC@hq.dhs.gov* or 202–987–9802.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under section 10(a) of the Federal Advisory Committee Act (FACA), Public Law 92–463 (5 U.S.C. ch. 10), which requires all FACA committee meetings to be open to the public unless the President, or the head of the Agency to which the advisory committee reports, determines that a portion of the meeting requires closing it to the public in accordance with 5 U.S.C. 552b(c).

The HSAPC provides organizationally independent, strategic, timely, specific, and actionable recommendations to the Secretary on key issues at the intersection of education, academia, and the DHS mission.

The open session will include: (1) remarks from senior DHS leaders and (2) briefings, public comment, member deliberation, and voting on the two draft reports from the Foreign Malign Influence in Higher Education and Combatting Online Child Sexual Exploitation and Abuse Subcommittees. The HSAPC was tasked to create these two subcommittees on November 14, 2023. The taskings can be found on the HSAPC website at *https://www.dhs.gov/hsapc.*

Members of the public will remain in listen-only mode except during the public comment session. Members of the public may register to attend this HSAPC meeting via Zoom by sending your full legal name and email address to Patrese Roberts via email to *HSAPC@hq.dhs.gov* or via phone at 202–987–9802 no later than 5 p.m. EST on Friday, May 31, 2024. Members of the public who have registered to attend will be provided the Zoom link, agenda, and the two draft subcommittee reports prior to the start of the meeting. For more information about the HSAPC, please visit our website: *https://www.dhs.gov/hsapc.*

For information on services for individuals with disabilities, or to request special assistance, please email *HSAPC@hq.dhs.gov* no later than 5 p.m. EST on Wednesday, May 29, 2024 or call 202–987–9802. The HSAPC is committed to ensuring all participants have equal access regardless of disability status. If you require a reasonable accommodation due to a disability to fully participate, please contact Patrese Roberts at 202–987–9802 or *HSAPC@hq.dhs.gov* as soon as possible.

Patrese Roberts,

Alternate Designated Federal Officer, Homeland Security Academic Partnership Council, U.S. Department of Homeland Security.

[FR Doc. 2024–10868 Filed 5–16–24; 8:45 am]

BILLING CODE 9112–FN–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Revision of Agency Information Collection Activity Under OMB Review: Baseline Assessment for Security Enhancement (BASE) Program

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-Day notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0062, abstracted below, to OMB for review and approval of a revision to the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. The collection allows TSA to conduct transportation security-related assessments during site visits with surface transportation security and operating officials.

DATES: Send your comments by June 17, 2024. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' and by using the find function.

FOR FURTHER INFORMATION CONTACT: Nicole Raymond, TSA PRA Officer, Information Technology, TSA–11, Transportation Security Administration, 6595 Springfield Center Drive, Springfield, VA 20598–6011; telephone (571) 227–2526; email *TSAPRA@tsa.dhs.gov.*

SUPPLEMENTARY INFORMATION: TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on November 13, 2023, 88 FR 77602.

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation will be available at *https://www.reginfo.gov* upon its submission to OMB. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

Title: Baseline Assessment for Security Enhancement (BASE) Program.

Type of Request: Revision of a currently approved collection.

OMB Control Number: 1652–0062.

Form(s): BASE electronic checklist.

Affected Public: Highway transportation asset owners and operators; and, public transportation agencies, including mass transit bus, rail transit, and less common types of service (such as cable cars, inclined planes, funiculars, and automated guideway systems).

Abstract: TSA's BASE program works with transportation asset and system owner/operators to identify their current security posture, identify security gaps, and encourage implementation of countermeasures applicable to the specific surface mode of transportation. Through a series of establish questions, data and results collected through the BASE program will inform TSA's policy and program initiatives and allow TSA to provide focused resources and tools to enhance the overall security posture within these sectors of the surface transportation community.

The Government Accountability Office (GAO), audit GAO–20–404, ''Passenger Rail Security: TSA Engages with Stakeholders but Could Better Identify and Share Standards and Key Practices (April 2020),'' recommended TSA update the BASE cybersecurity questions to ensure they reflect key practices.[1] TSA concurred with this recommendation and revised the collection to include questions that cover all five core functions of the National Institute of Standards and Technology cybersecurity framework. All core functions and a majority of the subcategories are integrated with Cybersecurity and Infrastructure Security Agency guidelines and established industry best practices in the newly-developed cybersecurity questions and cybersecurity BASE question sets, strengthening the cybersecurity health for the transportation sector.

Number of Respondents: 185.

Estimated Annual Burden Hours: 885 hours annually.[2]

Dated: May 14, 2024.

Nicole Raymond,

TSA Paperwork Reduction Act Officer, Information Technology.

[FR Doc. 2024–10889 Filed 5–16–24; 8:45 am]

BILLING CODE 9110–05–P

[1] Additional information regarding this audit and the GAO's recommendations are available on the GAO's website using the audit number (GAO–20–0404) or at the following link: *https://www.gao.gov/products/gao-20-404.*

[2] The annual burden has decreased since the publication of the 60-day notice, which reported 1,708 annual hour burden (MT/PR BASE 1,196 hours annually + HWY BASE 512 hours annually).

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0023]

Agency Information Collection Activities; Revision of a Currently Approved Collection: Application To Register Permanent Residence or Adjust Status

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until June 17, 2024.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be submitted via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2009–0020. All submissions received must include the OMB Control Number 1615–0023 in the body of the letter, the agency name and Docket ID USCIS–2009–0020.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, telephone number (240) 721–3000 (This is not a toll-free number; comments are not accepted via telephone message.). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *http://www.uscis.gov,* or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

The information collection notice was previously published in the **Federal Register** on September 8, 2023, at 88 FR 62102, allowing for a 60-day public comment period. USCIS received eight comments in connection with the 60-day notice.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2009–0020 in the search box. Comments must be submitted in English, or an English translation must be provided. The comments submitted to USCIS via this method are visible to the Office of Management and Budget and comply with the requirements of 5 CFR 1320.12(c). All submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection Request:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Application to Register Permanent Residence or Adjust Status; Supplement A to Form I–485, Adjustment of Status Under Section 245(i); Supplement J, Confirmation of Bona Fide Offer or Request for Job Portability Under Section 204(j); National Interest Waiver.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–485, Supplement A, Supplement J, National Interest Waiver; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. The Form I–485 is used to request and determine eligibility for adjustment of permanent residence status. The Form I–485 Supplement A is used to adjust status under section 245(i) of the Immigration and Nationality Act (Act). The Form I–485 Supplement J is used if you are an employment-based applicant for adjustment of status who is filing or has previously filed a Form I–485 as the principal beneficiary of a valid Form I–140 in an employment-based immigrant visa category that requires a job offer, and you now seek, in connection with your Form I–485, to (1) confirm that the job offered in your Form I–140 is a bona fide offer you intent to accept or (2) request job portability under INA section 204(j) to a new, full-time permanent job offer that you intent to accept, once your Form I–485 is approved. The Physicians National Interest Waiver will be used to notify foreign physician applicants of the medical service requirements for national interest waiver physicians applying for adjustment of status.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–485 is 1,060,585 and the estimated hour burden per response is 6.86 hours; the estimated total number of respondents for the information collection Supplement A is 44,848 and the estimated hour burden per response is 0.88 hour; the estimated total number of respondents for the information collection Supplement J is 57,353 and the estimated hour burden per response is 0.6 hour; the estimated total number of respondents for the information collection Biometrics Processing is 1,060,585 and the estimated hour burden per response is 1.17 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 8,590,376 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $636,780,655.

Dated: May 13, 2024.

Samantha L. Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2024–10808 Filed 5–16–24; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7081–N–01]

60-Day Notice of Proposed Information Collection: OMB Circular A–11 Section 280 Customer Experience Clearance; OMB Control No.: 2511–0001

AGENCY: Office of the Chief Financial Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* July 16, 2024.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal.

Written comments and recommendations for the proposed information collection can be sent within 60 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 60-day Review—Open for Public Comments'' or by using the search function. Interested persons are also invited to submit comments regarding this proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410; telephone (202) 402–3577 (this is not a toll-free number) or email: *PaperworkReductionActOffice@hud.gov.*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street, SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone (202) 402–3400. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit: *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Renewal of OMB Circular A–11 Section 280 Customer Experience Clearance.

OMB Approval Number: 2511–0001.

OMB Expiration Date: 09/30/2024.

Type of Request: Extension of an existing collection.

Form Number: None.

Description of the need for the information and proposed use: Under the 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. ''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 requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of

information, before submitting the collection to OMB for approval. To comply with this requirement, HUD is publishing notice of the proposed collection of information set forth in this document.

Whether seeking a loan, Social Security benefits, veterans' benefits, or other services provided by the Federal Government, individuals and businesses expect Government customer services to be efficient and intuitive, just like services from leading private-sector organizations. Yet the 2016 American Consumer Satisfaction Index and the 2017 Forrester Federal Customer Experience Index show that, on average, Government services lag nine percentage points behind the private sector.

A modern, streamlined and responsive customer experience means: Raising government-wide customer experience to the average of the private sector service industry; developing indicators for high-impact Federal programs to monitor progress towards excellent customer experience and mature digital services; and providing the structure (including increasing transparency) and resources to ensure customer experience is a focal point for agency leadership. To support this, OMB Circular A–11 Section 280 established government-wide standards for mature customer experience organizations in government and measurement. To enable Federal programs to deliver the experience taxpayers deserve, they must undertake three general categories of activities: Conduct ongoing customer research, gather and share customer feedback, and test services and digital products.

These data collection efforts may be either qualitative or quantitative in nature or may consist of mixed methods. Additionally, data may be collected via a variety of means, including but not limited to electronic or social media, direct or indirect observation (*i.e.,* in person, video and audio collections), interviews, questionnaires, surveys, and focus groups. HUD will limit its inquiries to data collections that solicit strictly voluntary opinions or responses. Steps will be taken to ensure anonymity of respondents in each activity covered by this request.

The results of the data collected will be used to improve the delivery of Federal services and programs. It will include the creation of personas, customer journey maps, and reports and summaries of customer feedback data and user insights. It will also provide government-wide data on customer experience that can be displayed on *performance.gov* to help build transparency and accountability of Federal programs to the customers they serve.

Respondents: Collections will be targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future. For the purposes of this request, ''customers'' are individuals, businesses, and organizations that interact with a Federal Government agency or program, either directly or via a Federal contractor. This could include individuals or households; businesses or other for-profit organizations; not-for-profit institutions; State, local or tribal governments; Federal government; and Universities.

Estimated Number of Respondents: 1,500,000.

Estimated Number of Responses: 1,500,000.

Frequency of Response: One time per collection.

Average Hours per Response: Varied, dependent upon the data collection method used. The possible response time to complete a questionnaire or survey may be 3 minutes or up to 2 hours to participate in an interview.

Estimated Burden: 75,000.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Joseph Carter,

Customer Experience Strategist, Office of the Chief Financial Officer.

[FR Doc. 2024–10875 Filed 5–16–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6331–N–02D]

Extension of Public Interest, General Applicability Tribal Consultation Waiver of Build America, Buy America Provisions as Applied to Tribal Recipients of HUD Federal Financial Assistance

AGENCY: Office of the Secretary, Department of Housing and Urban Development (HUD or the Department).

ACTION: Notice.

SUMMARY: In accordance with the Build America, Buy America Act (BABA or the Act), this notice advises that HUD is proposing an extension to the previously issued public interest, general applicability Tribal Consultation waiver until September 30, 2024 of the Build America, Buy America Act (BABA) Domestic Content Procurement Preference (the Buy America Preference or the BAP) as applied to Federal Financial Assistance (FFA) provided to Tribes, Tribally Designated Housing Entities (TDHEs), and other Tribal Entities (hereinafter collectively, Tribal Recipients). This proposed waiver extension is critical in keeping with the Federal Government's commitment to consult with Tribes and build Tribal capacity as established through Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, before applying the Buy America preference to programs that affect Tribal communities.

DATES: HUD published this proposed waiver extension on its website on May 10, 2024. Comments on the proposed waiver set out in this document are due on or before June 17, 2024. HUD will consider comments received and announce any formal adoption of this proposed waiver extension through a subsequent notice. If made final, the waiver extension would apply to awards obligated or incrementally funded on or after the effective date of the waiver extension until September 30, 2024. In the case of awards obligated prior to the effective date, the proposed waiver extension would apply to expenditures on or after the effective date of the waiver extension.

ADDRESSES: Interested persons are invited to submit comments on the general applicability waiver. Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov.* To receive consideration as public comments, comments must be submitted through one of two methods, specified below.

All submissions must refer to the above docket number and title.

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

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

No Facsimile Comments. Facsimile (FAX) comments will not be accepted.

Public Inspection of Comments. All properly submitted comments 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 above address. 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).

Copies of all submissions are available for inspection and downloading at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Faith Rogers, Department of Housing and Urban Development, 451 Seventh Street SW, Room 10126, Washington, DC 20410–5000, at (202) 402–7082 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications relay-service-trs.* HUD encourages submission of questions about this document be sent to *BuildAmerica BuyAmerica@hud.gov.*

SUPPLEMENTARY INFORMATION:

I. Build America, Buy America

The Build America, Buy America Act was enacted on November 15, 2021, as part of the Infrastructure Investment and Jobs Act (IIJA) (Pub. L. 117–58). The Act establishes a domestic content procurement preference, the BAP, for Federal infrastructure programs. Section 70914(a) of the Act establishes that no later than 180 days after the date of enactment, HUD must ensure that none of the funds made available for infrastructure projects may be obligated by the Department unless it has taken steps to ensure that the iron, steel, manufactured products, and construction materials used in a project are produced in the United States. In section 70912, the Act further defines a project to include ''the construction, alteration, maintenance, or repair of infrastructure in the United States'' and includes within the definition of infrastructure those items traditionally included along with buildings and real property. Thus, starting May 14, 2022, new awards of HUD FFA, and any of those funds newly obligated by HUD then obligated by the grantee for infrastructure projects, are covered under BABA provisions of the Act, 41 U.S.C. 8301 note, unless covered by a waiver.

II. HUD's Progress in Implementation of the Act Generally

Since the enactment of the Act, HUD has worked diligently to develop a plan to fully implement the BAP across its FFA programs awarding funds to non-Tribal Recipients. HUD understands that advancing Made in America objectives is a continuous effort and believes setting forth a transparent schedule of future implementation in those programs provides industry partners and non-Tribal Recipients with the time and notice necessary to efficiently and effectively implement the BAP. HUD has announced detailed plans for the implementation of the new BAP requirements in connection with its award of FFA to non-Tribal Recipients in a manner designed to maximize coordination and collaboration to support long-term investments in domestic production. HUD continues its efforts to implement the Act in those programs consistent with the guidance and requirements of the Made in America Office of the Office of Management and Budget, including guidance concerning appropriate compliance with the BAP.

III. Waivers

Under section 70914(b), HUD and other Federal agencies have authority to waive the application of a domestic content procurement preference when (1) application of the preference would be contrary to the public interest, (2) the materials and products subject to the preference are not produced in the United States at a sufficient and reasonably available quantity or satisfactory quality, or (3) inclusion of domestically produced materials and products would increase the cost of the overall project by more than 25 percent. Section 70914(c) provides that a waiver under section 70914(b) must be published by the agency with a detailed written explanation for the proposed determination and provide a public comment period of not less than 15 days. Pursuant to section 70914(d)(2), when seeking to extend a waiver of general applicability, HUD is required to provide for a public comment period of not less than 30 days on the continued need such waiver.

In order to ensure orderly implementation of the BAP across HUD's FFA programs awarding funds to non-Tribal Recipients, HUD has provided public interest, general applicability phased implementation waivers and announced a corresponding implementation plan for all non-Tribal Recipients. As part of those efforts, HUD has published two general applicability, public interest waivers covering Exigent Circumstances and De Minimis and Small Grants, which can be found at *https://www.hud.gov/program_offices/general_counsel/build_america_buy_america/waiver.* Additionally, HUD previously published two general applicability, public interest waivers of the BAP in connection with FFA provided to Tribal Recipients [1] through May 22, 2024, to provide the agency with sufficient time to complete the Tribal consultation process regarding implementation of the BAP in connection with infrastructure projects, both generally and specifically in connection with FFA received from HUD. This proposed waiver extension is critical in keeping with the Federal Government's commitment to follow consultation policies established through Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, before

[1] For purposes of this waiver, the term ''Tribal Recipients'' includes all recipients of grants or loan guarantees administered by HUD's Office of Native American Programs. This includes Indian tribes and TDHEs receiving grants and loan guarantee assistance under the Native American Housing Assistance and Self-Determination Act's (NAHASDA's) Indian Housing Block Grant Program and Title VI Loan Guarantee Program, and Indian tribes and Tribal Organizations receiving Indian Community Development Block Grant funds under the Housing and Community Development Act of 1974. It also includes Federal Financial Assistance provided by HUD to the Department of Hawaiian Home Lands (DHHL) which receives annual grant funding under the Native Hawaiian Housing Block Grant (NHHBG) program.

applying the Buy America Preference to programs that affect Tribes.

IV. Tribal Infrastructure and HUD Programs

Many Tribal communities are without basic infrastructure such as roads, running water, and indoor plumbing. Critical infrastructure in many Tribal communities is severely deficient and in need of repair and modernization. Addressing infrastructure needs is especially difficult for Tribes due to challenges faced locating available supplies, suppliers, and construction labor necessary for development.

Some Alaska Native villages are located off the road system, have short construction seasons because of extreme weather, and must grapple with unique transportation limitations, including having to ship basic construction materials twice per year by barge or air freight at extremely elevated costs. These Tribes often report to HUD that it can be a major challenge to secure space on a barge for construction materials. At times, even when space is secured, any unexpected setbacks faced, such as loss of cargo, materials damaged through shipping, or miscalculation of the appropriate amount or quality of materials needed, can result in infrastructure and housing projects being delayed an entire construction season. A project can be delayed for six months or longer until the next barge or carrier can arrive, which results in significant cost overruns.

Annually, HUD provides over $1 billion in FFA to 574 Federally recognized Tribal Nations. The Indian Housing Block Grant and the Indian Community Development Block Grant programs are critical funding sources that allow the Federal Government to carry out its trust responsibilities and support affordable housing and infrastructure development in Tribal communities. Under these programs, HUD provides block grants to Tribal Recipients to address housing and infrastructure needs—particularly for the benefit of low- and moderate-income families. HUD anticipates that the BAP will apply to some projects funded under these programs. Accordingly, HUD must ensure that Tribal Recipients are able to effectively implement the BAP and transition to compliance.

V. HUD's Consultation Policy

HUD's ''Tribal Government-to-Government Consultation Policy,'' adopted in compliance with Executive Order 13175, ''Consultation with Indian Tribal Governments,'' outlines the internal procedures and principles HUD must follow when communicating and coordinating on HUD programs and activities that affect Native American Tribes. HUD's Tribal Consultation policy recognizes the right of Tribes to self-government and facilitates Tribal participation and input in HUD's implementation of programs and FFA directed to Tribal communities.

Consistent with its Tribal Government-to-Government Consultation Policy, HUD has actively participated in consultation efforts with respect to the applicability of the BAP to Tribal Recipients. Initially, on September 21, 2022, eight agencies participated in a joint consultation hosted by the White House Council on Native American Affairs to consult with Tribal Nations on discretionary BAP provisions and the waiver categories characterized in OMB initial implementation guidance M–22–11. Tribes were initially requested to provide written comments and feedback by October 20, 2022 for Federal agency consideration. The resulting comments were received by the White House Council and distributed to agencies on October 25, 2022.

Since that time, and in light of the comments received from the Tribal leaders and the progress the Department has made implementing the BAP in other FFA programs, HUD engaged in consultation with respect to specific plans for implementation of the BAP in HUD's FFA provided to Tribal Recipients consistent with HUD's Tribal Government-to-Government Consultation Policy [2] and with President Biden's ''Tribal Consultation and Strengthening Nation-to-Nation Relationships'' Memorandum.[3]

During the past year, HUD held a series of Tribal consultation sessions across the country to obtain feedback from Tribes on the likely impact of employing the BAP in HUD's Tribal programs. As a result, HUD received over 100 comments from Tribes throughout the nation. Consultation sessions were held at the following events:

- National Congress of American Indians Mid-Year session, Prior Lake, Minnesota, June 7, 2023;
- Southern Plains Indian Housing Association session, Durant, Oklahoma, July 11, 2023;
- Nevada/California Indian Housing Association, Sparks, Nevada, August 13–16, 2023;
- United Native American Housing Association conference, Salt Lake City, Utah, August 22–24, 2023;
- Northwest Indian Housing Association, Coeur d'Alene, Idaho, September 12–14, 2023;
- Affiliated Tribes of Northwest Indians Annual Meeting, Chehalis, Washington, September 18–21, 2023;
- HUD ONAP National Tribal Housing Summit, Saint Paul, Minnesota, October 31–November 2, 2023;
- National Congress of American Indians Conference, New Orleans, Louisiana, November 12–17, 2023;
- Alaska BIA Provider's Conference, Anchorage, AK, November 29, 2023.

In addition to conducting in-person Tribal consultation sessions, HUD invited Tribes to submit written comments to HUD. HUD received written comments from HUD's Tribal Intergovernmental Advisory Committee and other Tribal grantees. HUD continues to process and evaluate the comments received during this process.

VI. Public Interest in an Extension of HUD's General Applicability Waiver of the BAP for FFA Provided to Tribal Recipients

This proposed waiver extension permits the use of non-domestic iron, steel, manufactured products, and construction materials in such projects that may otherwise be prohibited under section 70914(a) of BABA for HUD Federal financial assistance agreements with Tribal Recipients. The proposed waiver extension would apply to awards obligated or incrementally funded on or after the effective date of the proposed waiver extension until September 30, 2024. In the case of awards obligated prior to the effective date, the proposed waiver extension would apply to expenditures on or after the effective date of the final waiver. HUD is seeking comment on the granting of a limited extension to HUD's existing public interest, general applicability waiver of the BAP in connection with HUD's FFA to Tribal Recipients for HUD to conduct additional Tribal Consultations. HUD proposes this limited extension to allow the Department sufficient time to both complete its own evaluation of comments received through the consultations described above consistent with HUD's Tribal Government-to-Government Consultation Policy and provide clear guidance and technical assistance to recipients so that they understand expectations for the conclusion of the waiver, as HUD transitions to full BABA compliance in a timely manner. This

[2] *https://www.hud.gov/program_offices/public_indian_housing/ih/regs/govtogov_tcp. See also* 81 FR 40893.

[3] *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/26/memorandum-on-tribal-consultation-and-strengthening-nation-to-nation-relationships/.*

approach is consistent with the policy of Executive Order 13175.

During the proposed waiver extension, HUD intends to complete its analysis of comments received during its own Tribal consultation sessions with Tribes concerning the application of the BAP and fully brief the Office of Management and Budget on all Tribal feedback received. After considering all Tribal feedback, HUD intends to publish additional programmatic guidance. The guidance will provide Tribal Recipients with additional information including how the BAP will apply to HUD's various Tribal programs, ways that Tribal Recipients can comply with the BAP, and the process that Tribal Recipients must follow to request BAP waivers. HUD will provide training resources to ensure that Tribal Recipients are in a good position to implement the BAP under HUD's Tribal programs. HUD will also use this extension period to provide additional technical assistance resources to ensure that Tribal Recipients can build capacity and be in a better position to comply with the BAP.

HUD intends to implement the BAP in a manner that advances the Made in America objectives while also ensuring that Tribal Sovereignty and Self-Determinations are respected and the treaty and trust obligations of the United States are honored. At the conclusion of this proposed limited extension, Tribal recipients will be expected to transition to full compliance with BABA requirements.

VII. Assessment of Cost Advantage of a Foreign-Sourced Product

Under OMB Memorandum M–24–02, ''Implementation Guidance on Application of the Buy America Preference in Federal Financial Assistance Programs for Infrastructure,'' published on October 25, 2023, agencies are expected to assess ''whether a significant portion of any cost advantage of a foreign-sourced product is the result of the use of dumped steel, iron, or manufactured products or the use of injuriously subsidized steel, iron, or manufactured products'' as appropriate and incompliance with applicable law, before granting a public interest waiver. HUD's analysis has concluded that this assessment is not applicable to this waiver, as this waiver is not based on the cost of foreign-sourced products.

VIII. Limited Duration of the Waiver

HUD remains committed to the successful implementation of the important Buy America Preference across its programs providing covered FFA for infrastructure projects, while recognizing the unique government-to-government relationship it has with Tribal Recipients receiving HUD FFA for infrastructure projects and the new directives set forth in Executive Order 14112. HUD is committed to engaging its Federal agency partners in a timely process as noted above to further this goal.

IX. Solicitation of Comments

As required under section 70914 of the Act, HUD is soliciting comment from the public on the proposed waiver extension announced in this notice for a period of 30 days. If made final, the proposed waiver extension would apply to awards obligated or incrementally funded on or after the effective date of the proposed waiver extension until September 30, 2024. In the case of awards obligated prior to the effective date, the waiver would apply to expenditures on or after the effective date of the final waiver.

Adrianne R. Todman,

Acting Secretary.

[FR Doc. 2024–10860 Filed 5–16–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7086–N–01]

60-Day Notice of Proposed Information Collection: Management Certification & Entity Profile; OMB Control No.: 2502–0305

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

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* July 16, 2024.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal.

Written comments and recommendations for the proposed information collection can be sent within 60 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 60-day Review—Open for Public Comments'' or by using the search function. Interested persons are also invited to submit comments regarding this proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410–5000; telephone 202–402–3577 (this is not a toll-free number) or email: *PaperworkReductionActOffice@hud.gov.*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Management Certification & Entity Profile.

OMB Approval Number: 2502–0305.

OMB Expiration Date: 09/30/2023.

Type of Request: Reinstatement, without change, of previously approved collection for which approval has expired.

Form Number: HUD–9832 Management Entity Profile; HUD–9839–a Project Owner's Certification for Owner-Managed Multifamily Housing Projects; HUD–9839–b Project Owner's/Management Agent's Certification for Multifamily Housing Projects for Identity-of-Interest or Independent Management Agents; HUD–9839–c Project Owner's/Borrower's Certification for Elderly Housing Projects Managed by Administrators.

Description of the need for the information and proposed use: Owners of HUD-held, -insured, or subsidized multifamily housing projects must provide information for HUD's oversight of management agents/entities.

Respondents: Property owners; project managers.

Estimated Number of Respondents: 30,791.

Estimated Number of Responses: 1,710.

Frequency of Response: 1.

Average Hours per Response: Varies.

Total Estimated Burden: 1,710.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Jeffrey D. Little,

General Deputy Assistant Secretary, Office of Housing.

[FR Doc. 2024–10885 Filed 5–16–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R4–ES–2024–0069; FXES11140400000–245–FF04EF4000]

Receipt of Incidental Take Permit Application and Proposed Habitat Conservation Plan for the Sand Skink and Blue-Tailed Mole Skink; Osceola County, FL; Categorical Exclusion

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments and information.

SUMMARY: We, the Fish and Wildlife Service (Service), announce receipt of an application from the Osceola County Board of County Commissioners (applicant) for an incidental take permit (ITP) under the Endangered Species Act. The applicant requests the ITP to take the federally listed sand skink and blue-tailed mole skink incidental to the construction of a fire station in Osceola County, Florida. We request public comment on the application, which includes the applicant's proposed habitat conservation plan (HCP), and on the Service's preliminary determination that the proposed permitting action may be eligible for a categorical exclusion pursuant to the Council on Environmental Quality's National Environmental Policy Act (NEPA) regulations, the Department of the Interior's (DOI) NEPA regulations, and the DOI Departmental Manual. To make this preliminary determination, we prepared a draft environmental action statement and low-effect screening form, both of which are also available for public review. We invite comment from the public and local, State, Tribal, and Federal agencies.

DATES: We must receive your written comments on or before June 17, 2024.

ADDRESSES:

Obtaining Documents: The documents this notice announces, as well as any comments and other materials that we receive, will be available for public inspection online in Docket No. FWS–R4–ES–2024–0069 at *https://www.regulations.gov.*

Submitting Comments: If you wish to submit comments on any of the documents, you may do so in writing by one of the following methods:

- *Online: https://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–R4–ES–2024–0069; or
- *U.S. mail:* Public Comments Processing, Attn: Docket No. FWS–R4–ES–2024–0069; U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

FOR FURTHER INFORMATION CONTACT: Alfredo Begazo, by U.S. mail (see **ADDRESSES**), by telephone at 772–226–8134, or via email at *afredo_begazo@fws.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: We, the Fish and Wildlife Service (Service), announce receipt of an application from the Osceola County Board of County Commissioners (applicant) for an incidental take permit (ITP) under the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The applicant requests the ITP to take the federally listed sand skink (*Neoseps reynoldsi*) and blue-tailed mole-skink (*Eumeces egregius lividus*) (skinks) incidental to the construction and operation of a fire station in Osceola County, Florida. We request public comment on the application, which includes the applicant's habitat conservation plan (HCP), and on the Service's preliminary determination that this proposed ITP qualifies as low effect, and may qualify for a categorical exclusion pursuant to the Council on Environmental Quality's National Environmental Policy Act (NEPA) regulations (40 CFR 1501.4), the Department of the Interior's (DOI) NEPA regulations (43 CFR part 46), and the DOI's Departmental Manual (516 DM 8.5(C)(2)). To make this preliminary determination, we prepared a draft environmental action statement and low-effect screening form, both of which are also available for public review.

Proposed Project

The applicant requests a 5-year ITP to take skinks via the conversion of approximately 2.82 acres (ac) of occupied nesting, foraging, and sheltering habitat incidental to the construction of a fire station on a 4.2-ac parcel listed by the Osceola County Property Appraiser as 03–25–27–3359–0001–0010, in Osceola County, Florida. The applicant proposes to mitigate for take of the skinks by purchasing credits equivalent to 5.64 ac of skink-occupied habitat from a Service-approved conservation bank. The Service would require the applicant to purchase the credits prior to engaging in any phase of the project.

Our Preliminary Determination

The Service has made a preliminary determination that the applicant's project—including the construction of a fire station, driveways, parking spaces, green areas, stormwater pond, and associated infrastructure (*e.g.,* electric, water, and sewer lines)—would individually and cumulatively have a minor or negligible effect on the skinks and the environment. Therefore, we have preliminarily determined that the proposed ESA section 10(a)(1)(B) permit would be a low-effect ITP that individually or cumulatively would have a minor effect on the skinks and may qualify for application of a categorical exclusion pursuant to the Council on Environmental Quality's

NEPA regulations, DOI's NEPA regulations, and the DOI Departmental Manual. A low-effect incidental take permit is one that would result in (1) minor or negligible effects on species covered in the HCP; (2) nonsignificant effects on the human environment; and (3) impacts that, when added together with the impacts of other past, present, and reasonably foreseeable actions, would not result in significant cumulative effects to the human environment.

Next Steps

The Service will evaluate the application and the comments to determine whether to issue the requested permit. We will also conduct an intra-Service consultation pursuant to section 7 of the ESA to evaluate the effects of the proposed take. After considering the preceding and other matters, we will determine whether the permit issuance criteria of section 10(a)(1)(B) of the ESA have been met. If met, the Service will issue ITP number PER4412845 to the Osceola County Board of County Commissioners.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, be aware that your entire comment, including your personal identifying information, may be made available to the public. While you may request that we withhold your personal identifying information, we cannot guarantee that we will be able to do so.

Authority

The Service provides this notice under section 10(c) of the Endangered Species Act (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.32), and the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations (40 CFR 1500–1508 and 43 CFR part 46).

Robert L. Carey,

Division Manager, Environmental Review, Florida Ecological Services Office.

[FR Doc. 2024–10891 Filed 5–16–24; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LM_UT_FRN_MO4500178873]

Notice of Public Meeting, San Rafael Swell Recreation Area Advisory Council, Utah

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act, the Federal Advisory Committee Act, and the Federal Lands Recreation Enhancement Act, the Bureau of Land Management's (BLM's) San Rafael Swell Recreation Area Advisory Council (Council) will meet as indicated below.

DATES: The Council will participate in a field tour on August 13, 2024, from 8:30 a.m. to 4:00 p.m. Mountain Time (MT), and a public meeting with a virtual public comment participation option on August 14, 2024, at the Orangeville Community Center from 8:30 a.m. to 4:30 p.m. MT. Public comments will be accepted at 2:45 p.m. The meeting and field tour will be open to the public.

ADDRESSES: The August 13 field tour will commence and conclude, and the August 14 meeting will be held, at the Orangeville Community Center, 80 North Main Street, Orangeville, Utah 84537. Individuals that prefer to participate virtually in the public comment period must register in advance. Registration information will be posted two weeks in advance of the meeting at *https://www.blm.gov/get-involved/resource-advisory-council/near-you/utah/San-Rafael-Swell-RAC.*

Written comments may be sent prior to each meeting either by mail to the BLM Green River District, Attn: Lisa Everett, 170 South 500 West, Vernal, UT 84078, or by email at *utprmail@blm.gov,* with the subject line ''San Rafael Swell Recreation Area Advisory Council Meeting.''

FOR FURTHER INFORMATION CONTACT: BLM Green River Deputy District Manager Lisa Everett, by telephone at (435) 781–4400, or email at *utprmail@blm.gov.* Persons in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The John D. Dingell, Jr. Conservation, Management, and Recreation Act (Pub. L. 116–9) established the San Rafael Swell Recreation Area Advisory Council to advise the Secretary of the Interior, through the BLM, in planning and managing the San Rafael Swell Recreation Area. The seven-member Council represents a wide range of interests including local government, recreational users, grazing allotment permittees, conservation organizations, people with expertise in historical uses of the recreation area, and Tribal Nations.

Individuals who need special assistance, such as sign language interpretation and other reasonable accommodations, should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice at least seven days in advance. Agenda items for the August 14, 2024, meeting include an overview of the Dingell Act, camping management, supplemental rules, and other topics as appropriate. The August 13, 2024, field tour will visit various points within the San Rafael Swell Recreation Area and will include discussions of BLM management of public lands, focusing on options for camping management. Members of the public are welcome on the field tour but must provide their own transportation and meals. Individuals who plan to attend must RSVP to the BLM Green River District Office at least one week in advance of the field tour to the contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Detailed meeting minutes will be maintained in the BLM Green River District Office and will be made available for public inspection and reproduction during regular business hours within 90 days following each meeting. Minutes will also be posted to the Council's web page at *https://www.blm.gov/get-involved/resource-advisory-council/near-you/utah/San-Rafael-Swell-RAC.* The amount of time for individual oral comments may be limited depending on the total number of commenters. Written comments may also be sent to the BLM Green River Deputy District Manager at the address listed in the **ADDRESSES** section of this notice. All comments received will be provided to the Council.

Public Disclosure of Comments: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 5 U.S.C. ch. 10.

Gregory Sheehan,

State Director.

[FR Doc. 2024–10796 Filed 5–16–24; 8:45 am]

BILLING CODE 4331–25–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_MT_FRN_MO4500179599]

Public Meeting of the Western Montana Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act of 1976 and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM) Western Montana Resource Advisory Council (Council) will meet as follows.

DATES: The Council will participate in a field tour on June 26, 2024, from 12 p.m. to 4 p.m. mountain time (MT) and hold a business meeting on June 27, 2024, from 9 a.m. to 4 p.m. MT in Missoula, Montana. A virtual participation option will be available on June 27, 2024. Individuals who want to participate virtually must register at least 1 week in advance of the meeting to allow the BLM to plan for the number of individuals who wish to participate.

ADDRESSES: The meeting will be held, and the field tour will commence and conclude, at the Holiday Inn, 200 South Pattee, Missoula, MT 59802. The final agenda and virtual participation instructions will be confirmed for the public via BLM news release, social media, on the Council's web page at *https://www.blm.gov/get-involved/resource-advisory-council/near-you/montana-dakotas/western-montana-rac,* and through personal contact at least 2 weeks prior to the meeting.

Written comments for the Council may be sent electronically in advance of the scheduled meeting to Public Affairs Specialist David Abrams at *dabrams@blm.gov,* or in writing to BLM Western Montana District/Public Affairs, 101 N Parkmont, Butte, MT 59701.

FOR FURTHER INFORMATION CONTACT: David Abrams, BLM Western Montana District Office, telephone: (406) 437–2562, email: *dabrams@blm.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services for contacting Mr. Abrams. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The Council provides recommendations to the Secretary of the Interior concerning the planning and management of the public land resources located within the BLM's Western Montana District. The June 26, 2024, field tour will travel to points of interest within the Missoula Field Office. Members of the public are welcome on the field tour but must provide their own transportation and meals. Agenda topics for the June 27, 2024, meeting include a report from the Madison River Fee Proposal Subcommittee, and presentations on wildlife migration corridors, the Grizzly Bear Food Storage Order, and other resource management issues the Council may raise.

The meeting and field tour are open to the public and a 30-minute public comment period will be offered at 3:15 p.m. MT during the June 27, 2024, meeting. Depending on the number of persons wishing to speak and the time available, the amount of time for oral comments may be limited.

Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. We ask that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice at least 7 business days prior to the meeting to give the BLM sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

Before including your address, phone number, email address, or other personal identifying information in written comments, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. While the meeting is scheduled from 9 a.m. to 4 p.m. MT, it may end earlier or later depending on the needs of group members. Therefore, members of the public interested in a specific agenda item or discussion should schedule their arrival accordingly.

Detailed minutes for Council meetings will be maintained in the BLM Western Montana District Office. Minutes will also be posted to the Council's web page at *https://www.blm.gov/get-involved/resource-advisory-council/near-you/montana-dakotas/western-montana-rac.*

(Authority: 43 CFR 1784.4–2)

Kathryn Stevens,

Western Montana BLM District Manager.

[FR Doc. 2024–10917 Filed 5–16–24; 8:45 am]

BILLING CODE 4331–20–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_WY_FRN_MO #4500179801]

Filing of Plats of Survey, Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of official filing.

SUMMARY: The Bureau of Land Management (BLM) is scheduled to file plats of survey 30 calendar days from the date of this publication in the BLM Wyoming State Office, Cheyenne, Wyoming. These surveys, which were executed at the request of the U.S. Forest Service, the Bureau of Reclamation and the BLM are necessary for the management of these lands.

DATES: Protests must be received by the BLM prior to the scheduled date of official filing by June 17, 2024.

ADDRESSES: You may submit written protests to the Wyoming State Director at WY926, Bureau of Land Management, 5353 Yellowstone Road, Cheyenne, Wyoming 82009.

FOR FURTHER INFORMATION CONTACT: Sonja Sparks, BLM Wyoming Chief Cadastral Surveyor, by telephone at 307–775–6225 or by email at *s75spark@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 1–800–877–8339 to contact this office during normal business hours. The Service is available 24 hours a day, 7 days a week, to leave a message or question with this office. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The plats of survey of the following described lands are scheduled to be officially filed in the BLM Wyoming State Office, Cheyenne, Wyoming.

Sixth Principal Meridian, Wyoming

T. 41 N., R. 107 W., Group No. WY1061, dependent resurvey and metes-and-bounds survey, accepted January 9, 2024.
T. 41 N., R. 67 W., Group No. WY1059, dependent resurvey, accepted January 24, 2024;
T. 19 N., R. 79 W., Group No. 1058, corrective dependent resurvey and dependent resurvey, accepted January 24, 2024;
T. 40 N., R. 79 W., Group No. 1062, dependent resurvey and survey,

accepted January 30, 2024;
T. 23 N., R. 93 W., Group No. 1048, dependent resurvey and survey, accepted February 21, 2024;
T. 36 N., R. 79 W., Group No. 1065, dependent resurvey and survey, accepted March 5, 2024;
T. 16 N., R. 78 W., Group No. 1060, dependent resurvey and survey, accepted March 21, 2024;
T. 15 N., R. 81 W., Group No. 1068, dependent resurvey, accepted March 21, 2024;
T. 16 N., R. 82 W., Group No. 1068, dependent resurvey, accepted March 21, 2024;
T. 18 N., R. 81 W., Group No. 1045, dependent resurvey and survey, accepted March 21, 2024;
T. 51 N., R. 76 W., Group No. 1085, dependent resurvey and survey, accepted April 12, 2024;
T. 52 N., R. 75 W., Group No. 1085, dependent resurvey, accepted April 12, 2024;
T. 52 N., R. 76 W., Group No. 1085, dependent resurvey, accepted April 12, 2024;

Wind River Meridian, Wyoming

T. 3 N., R. 1 E., Group No. 1084, dependent resurvey and survey, accepted April 16, 2024;
T. 4 N., R. 4 E., Group No. 1084, dependent resurvey and survey, accepted April 16, 2024;
T. 5 N., R. 5 E., Group No. 1084, remonumentation and dependent resurvey, accepted April 16, 2024;
T. 5 N., R. 6 E., Group No. 1084, remonumentation and dependent resurvey, accepted April 16, 2024;
T. 6 N., R. 5 E., Group No. 1084, remonumentation and dependent resurvey, accepted April 16, 2024 ;
T. 6 N., R. 6 E., Group No. 1084, remonumentation and dependent resurvey, accepted April 12, 2024;
T. 7 N., R. 5 E., Group No. 1084, remonumentation and dependent resurvey, accepted April 16, 2024.

A person or party who wishes to protest one or more plats of survey identified in this notice must file a written notice of protest within 30 calendar days from the date of this publication with the Wyoming State Director at the above address. Any notice of protest received after the scheduled date of official filing will be untimely and will not be considered. A written statement of reasons in support of a protest, if not filed with the notice of protest, must be filed with the State Director within 30 calendar days after the notice of protest is filed. If a notice of protest against a plat of survey is received prior to the scheduled date of official filing, the official filing of the plat of survey identified in the notice of protest will be stayed pending consideration of the protest. A plat of survey will not be officially filed until the next business day following dismissal or resolution of all protests of the plat.

Before including your address, phone number, email address, or other personal identifying information in your protest, you should be aware that your entire protest—including your personal identifying information—may be made publicly available at any time. While you can ask us to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Copies of the preceding described plat and field notes are available to the public at a cost of $4.20 per plat and $0.15 per page of field notes. Requests can be made to *blm_wy_survey_records@blm.gov* or by telephone at 307–775–6222.

(Authority: 43 U.S.C., chapter 3)

Dated: May 14, 2024.

Sonja S. Sparks,

Chief Cadastral Surveyor of Wyoming.

[FR Doc. 2024–10903 Filed 5–16–24; 8:45 am]

BILLING CODE 4331–26–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_WY_FRN_MO4500178570]

Notice of Availability of the Proposed Resource Management Plan Amendment and Final Supplemental Environmental Impact Statement for the Buffalo Field Office, Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended (FLMPA), the Bureau of Land Management (BLM) has prepared a Proposed Resource Management Plan (RMP) Amendment and Final Supplemental Environmental Impact Statement (EIS) for federal coal managed by the Buffalo Field Office and by this notice is announcing the opportunity to protest the Proposed RMP Amendment.

DATES: The BLM Director will consider protests to the Proposed RMP Amendment. Protests must be postmarked or electronically submitted on the BLM's ePlanning site within 30 days after the Environmental Protection Agency's (EPA) publication of a Notice of Availability (NOA) of the Proposed RMP Amendment and Final EIS in the **Federal Register**. The EPA usually publishes NOAs on Fridays.

ADDRESSES: The Proposed RMP Amendment and Final Supplemental EIS are available for review on the BLM ePlanning project website at *https://eplanning.blm.gov/eplanning-ui/project/2021239/510.*

Instructions for filing a protest on the Proposed RMP Amendment can be found at *https://www.blm.gov/programs/planning-and-nepa/public-participation/filing-a-plan-protest* and at 43 CFR 1610.5–2. All protests must be submitted in writing and mailed to one of the following by any one of the following methods:

- *Website: https://eplanning.blm.gov/eplanning-ui/project/2021239/510.*
- *Regular and Overnight Mail:* BLM Director, Attention: Protest Coordinator (HQ210), Denver Federal Center, Building 40 (Door W–4), Lakewood, CO 80215.

FOR FURTHER INFORMATION CONTACT: Thomas Bills, Project Manager, telephone (307) 684–1133; or at the address BLM Buffalo Field Office, 1425 Fort Street, Buffalo WY 82834; email *tbills@blm.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The BLM prepared the Proposed Plan Amendment and Final Supplemental EIS to address a United States District Court for the District of Montana order (*Western Organization of Resource Councils, et al.* v. *BLM;* CV 00076–GF–BMM; 8/3/2022). The Final Supplemental EIS provides additional land use planning level analysis that considers no-leasing and limited coal leasing alternatives; discloses the public health impacts, both climate and non-climate, of burning fossil fuels (coal, oil, and gas); and completes new coal screens in accordance with 43 CFR 3420.1–4 to determine the lands to be made available for further consideration for coal leasing in the planning area.

The Buffalo planning area is located in Campbell, Johnson, and Sheridan Counties, Wyoming. The Coal Development Potential Area is located within Campbell County, Wyoming, and encompasses approximately 48 billion short tons of recoverable BLM-administered Federal coal.

The BLM analyzed three alternatives in detail, including the No Action Alternative and two alternatives that

vary the amount of BLM-administered Federal coal authorized to be available for leasing. The alternatives include:

- *Alternative A (the No Leasing Alternative):* the Coal Development Potential Area would be unavailable for leasing;
- *Alternative B (the No Action Alternative):* approximately 48.0 billion short tons of recoverable BLM-administered coal within the Coal Development Potential Area established in the 2019 RMP Amendment and Final Supplemental EIS would be available for further consideration of leasing; and
- *Alternative C:* a reduced level of coal (1.24 billion short tons of recoverable BLM-administered coal) would be available for leasing within the Coal Development Potential Area.

The BLM further considered three additional alternatives but dismissed them from detailed analysis, as explained in the Proposed RMP Amendment and Final Supplemental EIS.

The BLM selected Alternative A, the No Leasing Alternative, as the proposed plan for allocating BLM administered coal; under this alternative, no BLM administered coal would be available for leasing within the Buffalo Field Office planning area. The proposed plan does not affect the area with coal development potential or the area determined to be suitable for surface coal mining. Collectively, the mines have sufficient federal coal leased to meet forecasted production levels into 2041. The remaining leased coal volume provides time to advance commercial scale carbon capture and non-thermal coal use technologies during the planning period.

The BLM published a notice of availability for the Draft Supplemental EIS and Potential RMP Amendment in the **Federal Register** on May 8, 2023, which initiated a 90-day comment period (88 FR 29691). On May 31, the BLM hosted a public meeting in Gillette, Wyoming, to present the Draft Supplemental EIS and RMP Amendment to the public and solicit comments. The BLM also hosted an on-line public meeting on June 5, 2023.

During the public comment period, the BLM received 25 unique written submissions containing 147 substantive comments. The Draft Supplemental EIS comments helped the BLM refine the Final Supplemental EIS and guided the development of the Proposed RMP Amendment.

Protest of the Proposed RMP

The BLM planning regulations state that any person who participated in the preparation of the RMP and has an interest that will or may be adversely affected by approval of the Proposed RMP may protest its approval. Protest of the Proposed RMP constitutes the final opportunity for administrative review of the proposed land use planning decisions prior to the BLM adopting an approved RMP. Instructions for filing a protest with the BLM Director may be found online at *https://www.blm.gov/programs/planning-and-nepa/public-participation/filing-a-plan-protest* and at 43 CFR 1610.5–2. All protests must be in writing and mailed to the appropriate address, as set forth in the **ADDRESSES** section earlier or submitted electronically through the BLM ePlanning project website as described previously. Protests submitted electronically by any means other than the ePlanning project website will be invalid unless a protest is also submitted as a hard copy. The BLM will render a written decision on each protest. The Director's protest decision shall be the final decision of the Department of the Interior. Responses to protest issues will be compiled and documented in a Protest Resolution Report made available following the protest resolution online at: *https://www.blm.gov/programs/planning-and-nepa/public-participation/protest-resolution-reports.* After resolution of protests, the BLM will issue a Record of Decision and Approved RMP.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 40 CFR 1506.6, 40 CFR 1506.10, 43 CFR 1610.2)

Andrew Archuleta,

State Director.

[FR Doc. 2024–10792 Filed 5–16–24; 8:45 am]

BILLING CODE 4331–20–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_MT_FRN_MO4500178570]

Notice of Availability of the Proposed Resource Management Plan Amendment and Final Supplemental Environmental Impact Statement for the Miles City Field Office, Montana

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) has prepared a Proposed Resource Management Plan (RMP) Amendment and Final Supplemental Environmental Impact Statement (EIS) for public lands managed by the Miles City Field Office and by this notice is announcing the opportunity to protest the Proposed RMP Amendment.

DATES: The BLM Director will consider protests to the Proposed RMP Amendment. Protests must be postmarked or electronically submitted on the BLM's ePlanning site within 30 days after the Environmental Protection Agency's (EPA) publication of a Notice of Availability (NOA) of the Proposed RMP Amendment and Final EIS in the **Federal Register**. The EPA usually publishes NOAs on Fridays.

ADDRESSES: The Proposed RMP Amendment and Final Supplemental EIS are available for review on the BLM ePlanning project website at *https://eplanning.blm.gov/eplanning-ui/project/2021155/510.* Documents pertinent to this proposal may be examined online at *https://eplanning.blm.gov/eplanning-ui/project/2021155/510* and at the Miles City Field Office.

Instructions for filing a protest on the Proposed RMP Amendment can be found at *https://www.blm.gov/programs/planning-and-nepa/public-participation/filing-a-plan-protest* and at 43 CFR 1610.5–2. All protests must be submitted in writing and mailed to one of the following by any one of the following methods:

- *Website: https://eplanning.blm.gov/eplanning-ui/project/2021155/510.*
- *Regular and Overnight Mail:* BLM Director, Attention: Protest Coordinator (HQ210), Denver Federal Center, Building 40 (Door W–4), Lakewood, CO 80215.

FOR FURTHER INFORMATION CONTACT: Irma Nansel, Project Manager, telephone

(406) 233–3653; or at the address BLM Miles City Field Office, 111 Garryowen Road, Miles City, MT 59301; email *inansel@blm.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The BLM prepared the Proposed Plan Amendment and Final Supplemental EIS to address a United States District Court for the District of Montana order (*Western Organization of Resource Councils, et al.* v. *BLM;* CV 00076–GF–BMM; 8/3/2022). The Final Supplemental EIS provides additional land use planning level analysis that considers no-leasing and limited coal leasing alternatives; discloses the public health impacts, both climate and non-climate, of burning fossil fuels (coal, oil, and gas); and completes new coal screens in accordance with 43 CFR 3420.1–4 to determine the lands to be made available for further consideration for coal leasing in the planning area.

The Miles City planning area is located in Carter, Custer, Daniels, Dawson, Fallon, Garfield, McCone, Powder River, Prairie, Richland, Roosevelt, Rosebud, Sheridan, Treasure, Wibaux, and portions of Big Horn and Valley Counties, Montana, and encompasses approximately 2.7 million surface acres of BLM-managed public land and 11.7 million acres of Federal coal mineral estate.

The BLM has analyzed four alternatives in detail, including the No Action Alternative and three alternatives that vary the amount of BLM-administered Federal coal available for further consideration for coal leasing.

The No Action Alternative is the decision from the 2019 Approved RMP Amendment, which identified approximately 1,214,380 acres of Federal coal as available for further consideration for coal leasing across the Miles City Field Office.

The action alternatives applied the coal screens (43 CFR 3420.1–4(e)) using current data and evaluated the issues identified through internal and public scoping. Application of coal screen 1 (development potential) identified approximately 1,745,000 Federal coal acres as having development potential. The action alternatives also address the NEPA deficiencies identified by the court order associated with the application of the multiple-use screen. Specifically, they apply a multiple-use climate change criterion that uses greenhouse gas emissions as a proxy for climate change. Reducing availability of Federal lands for coal leasing reduces the contribution of greenhouse gas emissions from the development and combustion of Federal coal from the planning area.

Alternative B analyzes approximately 69,310 acres of Federal coal as available for further consideration for coal leasing. Alternative C analyzes approximately 810 acres of Federal coal as available for further consideration for coal leasing, and Alternative D, the Proposed RMP, analyzes 0 (zero) acres of Federal coal as available for further consideration for coal leasing. The BLM revised the coal reasonably foreseeable development scenario from the 2015 Miles City RMP using the most current publicly available coal production data to forecast development during the planning period, which runs to 2038. The revised reasonably foreseeable development scenario was applied to all alternatives.

The BLM further considered one additional alternative but dismissed it from detailed analysis, as explained in the Final Supplemental EIS.

The BLM selected Alternative D as the proposed plan for allocating BLM administered coal; under this alternative, no Federal coal would be available for leasing within the Miles City Field Office planning area. The proposed plan does not affect the area with coal development potential or the area determined to be suitable for surface coal mining. The BLM has determined that additional leasing of Federal coal is not necessary based on the current analysis in the Final Supplemental EIS. The analysis indicates that operating mines in the planning area have existing leases with sufficient coal reserves to maintain existing mine production levels until 2035 for Spring Creek Mine and 2060 for Rosebud Mine.

The BLM published a notice of availability for the Draft Supplemental EIS and Potential RMP Amendment in the **Federal Register** on May 8, 2023 (88 FR 29689), which initiated a 90-day comment period. On June 6th, the BLM hosted a public meeting at the BLM Miles City Field Office in Miles City, Montana, to present the Draft Supplemental EIS and RMP Amendment to the public and solicit comments. The BLM also hosted an on-line public meeting on June 7, 2023. Eight members of the public attended the online meeting. During the public comment period, the BLM received 14 unique written submissions containing 167 substantive comments. The Draft Supplemental EIS comments helped the BLM refine the Final Supplemental EIS and guided the development of the Proposed RMP Amendment.

Protest of the Proposed RMP

The BLM planning regulations state that any person who participated in the preparation of the RMP and has an interest that will or may be adversely affected by approval of the Proposed RMP may protest its approval. Protest of the Proposed RMP constitutes the final opportunity for administrative review of the proposed land use planning decisions prior to the BLM adopting an approved RMP. Instructions for filing a protest with the BLM Director may be found online at *https://www.blm.gov/programs/planning-and-nepa/public-participation/filing-a-plan-protest* and at 43 CFR 1610.5–2. All protests must be in writing and mailed to the appropriate address, as set forth in the **ADDRESSES** section earlier or submitted electronically through the BLM ePlanning project website as described previously. Protests submitted electronically by any means other than the ePlanning project website will be invalid unless a protest is also submitted as a hard copy. The BLM will render a written decision on each protest. The Director's protest decision shall be the final decision of the Department of the Interior. Responses to protest issues will be compiled and documented in a Protest Resolution Report made available following the protest resolution online at: *https://www.blm.gov/programs/planning-and-nepa/public-participation/protest-resolution-reports.* After resolution of protests, the BLM will issue a Record of Decision and Approved RMP.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 40 CFR 1506.6, 40 CFR 1506.10, 43 CFR 1610.2)

Sonya I. Germann,

State Director.

[FR Doc. 2024–10793 Filed 5–16–24; 8:45 am]

BILLING CODE 4331–20–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNM930000.L14400000.BJ0000.BX0000]

Notice of Filing of Plats of Survey; New Mexico; Oklahoma

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of official filing.

SUMMARY: The plats of survey of the following described lands are scheduled to be officially filed 30 days after the date of this publication in the Bureau of Land Management, New Mexico State Office, Santa Fe, New Mexico. The surveys announced in this notice are necessary for the management of lands administered by the agency indicated.

ADDRESSES: These plats will be available for inspection in the New Mexico State Office, Bureau of Land Management, 301 Dinosaur Trail, Santa Fe, New Mexico 85004–4427. Protests of a survey should be sent to the New Mexico State Director at the above address.

FOR FURTHER INFORMATION CONTACT: Michael L. Hart, Acting Chief Cadastral Surveyor; (505) 761–8908; *mlhart@blm.gov.* Persons who use a telecommunications device for the deaf may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION:

New Mexico Principal Meridian, New Mexico

The plat representing the dependent resurvey of a tract of land in Township 25 South, Range 3 East, accepted March 11, 2024, for Group No. 1214, New Mexico.

This plat was prepared at the request of the Bureau of Land Management, Las Cruces District Office.

The plat representing the dependent resurvey and survey of a tract of land in Township 15 North, Range 12 East, accepted May 13, 2024, for Group No. 1219, New Mexico.

This plat was prepared at the request of the National Park Service.

Indian Meridian, Oklahoma

The plat representing the dependent resurvey and survey of a tract of land in Township 11 North, Range 8 West, accepted May 3, 2024, for Group No. 246, Oklahoma.

This plat was prepared at the request of the Bureau of Indian Affairs, Anadarko Agency, Oklahoma.

A person or party who wishes to protest against this survey must file a written notice of protest within 30 calendar days from the date of this publication with the New Mexico State Director, Bureau of Land Management, stating that they wish to protest.

A statement of reasons for a protest may be filed with the notice of protest to the State Director, or the statement of reasons must be filed with the State Director within 30 days after the protest is filed. Before including your address, or other personal information in your protest, please be aware that your entire protest, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 43 U.S.C. ch. 3.

Michael L. Hart,

Acting Chief Cadastral Surveyor of New Mexico and Oklahoma.

[FR Doc. 2024–10843 Filed 5–16–24; 8:45 am]

BILLING CODE 4331–23–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1381]

Certain Disposable Vaporizer Devices and Components and Packaging Thereof; Notice of a Commission Determination Not To Review Initial Determination Amending the Complaint and Notice of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (Order No. 19) issued by the chief administrative law judge (''CALJ'') granting a motion to amend the complaint and notice of investigation (''NOI'') to correct the mailing address associated with respondents Flawless Vape Shop Inc. and Flawless Vape Wholesale & Distribution Inc., both of Anaheim, CA (''the Flawless Respondents'').

FOR FURTHER INFORMATION CONTACT: Paul Lall, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2043. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal, telephone (202) 205–1810.

SUPPLEMENTARY INFORMATION: On December 20, 2023, the Commission instituted this investigation based on a complaint filed on behalf of complainants R.J. Reynolds Tobacco Company and R.J. Reynolds Vapor Company (collectively, ''Complainants''). 88 FR 88111–12 (Dec. 20, 2023). The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based upon the importation into the United States, and the sale of certain disposable vaporizer devices and components and packaging thereof by reason false advertising, false designation of origin, and unfair competition, the threat or effect of which is to destroy or substantially injure an industry in the United States. The Commission's NOI named the following twenty-five (25) respondents: the Flawless Respondents; Shenzhen Noriyang of Shenzhen, China; Affiliated Imports, LLC of Pflugerville, TX; American Vape Company, LLC a/k/a American Vapor Company, LLC of Pflugerville, TX; Breeze Smoke, LLC of West Bloomfield, MI; Dongguan (Shenzhen) Shikai Technology Co., Ltd. of Guangdong, China; EVO Brands, LLC of Wilmington, DE; Guangdong Qisitech Co., Ltd. of Dongguan City, China; iMiracle (Shenzhen) Technology Co. Ltd. of Shenzhen, China; Magellan Technology Inc. of Buffalo, NY; Pastel Cartel, LLC of Pflugerville, TX; Price Point Distributors Inc. d/b/a Prince Point NY of Farmingdale, NY; PVG2, LLC of Wilmington, DE; Shenzhen Daosen Vaping Technology Co., Ltd. of Shenzhen, China; Shenzhen Fumot Technology Co., Ltd. of Shenzhen, China; Shenzhen Funyin Electronic Co., Ltd. of Guangdong, China; Shenzhen Han Technology Co., Ltd. of Shenzhen, China; Shenzhen Innokin Technology Co., Ltd., of Shenzhen, China; Shenzhen IVPS Technology Co., Ltd. of Shenzhen, China; Shenzhen Weiboli Technology Co. Ltd. of Shenzhen, China; SV3 LLC d/b/a Mi-One Brands of Phoenix, AZ; Thesy, LLC d/b/a Element Vape of El

Monte, CA; Vapeonly Technology Co. Ltd. of Shenzhen, China; and VICA of Tustin, CA. *Id.* The Office of Unfair Import Investigations (''OUII'') was also named as a party in this investigation. *Id.*

On February 16, 2024, Complainants filed an unopposed motion to amend the complaint and NOI to correct the mailing address associated with the Flawless Respondents. On February 29, 2024, OUII filed a response supporting the motion.

On April 18, 2024, the CALJ issued the subject ID (Order No. 19) pursuant to Commission Rule 210.14(b) (19 CFR 210.14(b)), granting Complainants' motion to amend the complaint and NOI as requested. The ID finds that Complainants have established good cause for the proposed amendment, and that the amendment ''will not prejudice the public interest or the rights of any parties to the investigation.'' ID at 2.

No party filed a petition for review of the subject ID.

The Commission has determined not to review the subject ID (Order No. 19).

The Commission vote for this determination took place on Issued: May 13, 2024.

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: May 13, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–10837 Filed 5–16–24; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–712–715 and 731–TA–1679–1682 (Preliminary)]

Ferrosilicon from Brazil, Kazakhstan, Malaysia, and Russia; Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of ferrosilicon from Brazil, Kazakhstan, Malaysia, and Russia, provided for in subheadings 7202.21.10, 7202.21.50, 7202.21.75, 7202.21.90, and 7202.29.00 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value (''LTFV'') and imports of the subject merchandise from Brazil, Kazakhstan, Malaysia, and Russia that are alleged to be subsidized by the governments of Brazil, Kazakhstan, Malaysia, and Russia.[2]

Commencement of Final Phase Investigations

Pursuant to section 207.18 of the Commission's rules, the Commission also gives notice of the commencement of the final phase of its investigations. The Commission will issue a final phase notice of scheduling, which will be published in the **Federal Register** as provided in § 207.21 of the Commission's rules, upon notice from the U.S. Department of Commerce (''Commerce'') of affirmative preliminary determinations in the investigations under §§ 703(b) or 733(b) of the Act, or, if the preliminary determinations are negative, upon notice of affirmative final determinations in those investigations under §§ 705(a) or 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Any other party may file an entry of appearance for the final phase of the investigations after publication of the final phase notice of scheduling. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations. As provided in section 207.20 of the Commission's rules, the Director of the Office of Investigations will circulate draft questionnaires for the final phase of the investigations to parties to the investigations, placing copies on the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*), for comment.

Background

On March 28, 2024, CC Metals and Alloy, LLC, Calvert City, Kentucky, and Ferroglobe USA, Inc., Beverly, Ohio, filed petitions with the Commission and Commerce, alleging that an industry in the United States is materially injured or threatened with material injury by reason of subsidized imports of ferrosilicon from Brazil, Kazakhstan, Malaysia, and Russia and LTFV imports of ferrosilicon from Brazil, Kazakhstan, Malaysia, and Russia. Accordingly, effective March 28, 2024, the Commission instituted countervailing duty investigation Nos. 701–TA–712–715 and antidumping duty investigation Nos. 731–TA–1679–1682 (Preliminary).

Notice of the institution of the Commission's investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of April 4, 2024 (89 FR 23042). The Commission conducted its conference on April 18, 2024. All persons who requested the opportunity were permitted to participate.

The Commission made these determinations pursuant to §§ 703(a) and 733(a) of the Act (19 U.S.C. 1671b(a) and 1673b(a)). It completed and filed its determinations in these investigations on May 13, 2024. The views of the Commission are contained in USITC Publication 5506 (May 2024), entitled *Ferrosilicon from Brazil, Kazakhstan, Malaysia, and Russia: Investigation Nos. 701–TA–712–715 and 731–TA–1679–1682 (Preliminary).*

By order of the Commission.

Issued: May 13, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–10827 Filed 5–16–24; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Furnishing Documents to the Secretary of Labor on Request Under Employee Retirement Income Security Act

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.

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] 89 FR 31133 and 89 FR 31137 (April 24, 2024).

DATES: The OMB will consider all written comments that the agency receives on or before June 17, 2024.

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: Michael Howell by telephone at 202–693–6782, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: Prior to the enactment of the Taxpayer Relief Act of 1997 (Pub. L. 105–34, August 5, 1997) (TRA '97), section 104(a) of the Employee Retirement Security Act of 1974 (ERISA) required administrators of employee benefit plans automatically to file the plan's summary plan description (SPD) and any summaries of material modification (SMMs) with the Secretary of the Department of Labor (the Department). TRA '97 eliminated the requirement that these documents be filed automatically with the Department, but added ERISA section 104(a)(6), requiring a plan administrator to furnish documents related to an employee benefit plan to the Department upon request. The requirement that administrators furnish the Department requested plan documents other than SPDs and SMMs was part of section 104(a) prior to enactment of TRA '97; that requirement was moved by TRA '97 to section 104(a)(6) and consolidated with the new furnishing requirement pertaining to SPDs and SMMs.

Pursuant to the regulation, the Department requests documents under section 104(a)(6) when a participant or beneficiary has previously requested the documents directly from the plan administrator and the administrator has failed or refused to provide them. The Department therefore uses the requested information to respond to participants' requests to the Department for documents that the participants were unable to obtain from their plan administrators. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on August 25, 2023 (88 FR 58312).

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

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: Furnishing Documents to the Secretary of Labor on Request Under Employee Retirement Income Security Act Section 104(a)(6).

OMB Control Number: 1210–0112.

Affected Public: Businesses or other for-profits.

Total Estimated Number of Respondents: 1,181.

Total Estimated Number of Responses: 1,181.

Total Estimated Annual Time Burden: 53 hours.

Total Estimated Annual Other Costs Burden: $826.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Michael Howell,

Senior Paperwork Reduction Act Analyst.

[FR Doc. 2024–10806 Filed 5–16–24; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Grain Handling Facilities Standard

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Occupational Safety & Health Administration (OSHA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before June 17, 2024.

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: Nicole Bouchet by telephone at 202–693–0213, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The information collection requirements are directed toward assuring the safety of workers in grain handling through development of a housekeeping plan, an emergency action plan, procedures for the use of tags and locks, the issuance of hot work permits, and permits for entry into grain storage structures. Certification records are required after inspections of the mechanical and safety control equipment associated with dryers, grain stream processing equipment, etc. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on February 23, 2024 (89 FR 13753).

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition,

notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–OSHA.

Title of Collection: Grain Handling Facilities Standard.

OMB Control Number: 1218–0206.

Affected Public: Farms.

Total Estimated Number of Respondents: 14,940.

Total Estimated Number of Responses: 1,105,635.

Total Estimated Annual Time Burden: 57,837 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Nicole Bouchet,

Certifying Official.

[FR Doc. 2024–10794 Filed 5–16–24; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Powered Industrial Trucks Standard

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Occupational Safety & Health Administration (OSHA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before June 17, 2024.

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: Nicole Bouchet by telephone at 202–693–0213, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The Powered Industrial Trucks Standard contains several information collection requirements addressing truck design, construction, and modification, as well as certification of training and evaluation for truck operators. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on February 23, 2024 (89 FR 13752).

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–OSHA.

Title of Collection: Powered Industrial Trucks Standard.

OMB Control Number: 1218–0242.

Affected Public: Private Sector—Businesses or other for-profits.

Total Estimated Number of Respondents: 1,239,687.

Total Estimated Number of Responses: 2,451,732.

Total Estimated Annual Time Burden: 437,198 hours.

Total Estimated Annual Other Costs Burden: $262,774.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Nicole Bouchet,

Certifying Official.

[FR Doc. 2024–10795 Filed 5–16–24; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Cognitive and Psychological Research

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Bureau of Labor Statistics (BLS)-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 June 17, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Nicole Bouchet by telephone at 202–693–0213, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The Bureau of Labor Statistics' Behavioral Science Research Center (BSRC) conducts psychological research focusing on the design and execution of the data collection process in order to improve the quality of data collected by the Bureau. The BSRC conducts

research aimed at improving data collection quality by assessing questionnaire/form management and administration, as well as issues which relate to interviewer training and interaction with respondents in the interview process. BSRC staff work closely with economists and/or program specialists responsible for defining the concepts to be measured by the Bureau of Labor Statistics' collection programs. The proposed laboratory research will be conducted from Fiscal Year (FY) 2024 through FY 2027 to enhance data quality in the Bureau of Labor Statistics' surveys. Improvements will be made by examining psychological and cognitive aspects of BLS's data collection procedures, including questionnaire design, interviewing procedures, collection modalities, and administrative technology. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on December 14, 2023 (88 FRN 86681).

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.

Agency: DOL–BLS.

Title of Collection: Cognitive and Psychological Research.

OMB Control Number: 1220–0141.

Affected Public: Individuals or Households, State, Local and Tribal Governments, Businesses or other for-profits, Not-for-profit institutions.

Total Estimated Number of Respondents: 31,350.

Total Estimated Number of Responses: 31,350.

Total Estimated Annual Time Burden: 11,349 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Nicole Bouchet,

Senior Paperwork Reduction Act Analyst.

[FR Doc. 2024–10807 Filed 5–16–24; 8:45 am]

BILLING CODE 4510–24–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request

AGENCY: National Science Foundation.

ACTION: Submission for OMB review; comment request.

SUMMARY: The National Science Foundation (NSF) has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1995. This is the second notice for public comment; the first was published in the **Federal Register**, and no comments were received. NSF is forwarding the proposed submission to the Office of Management and Budget (OMB) for clearance simultaneously with the publication of this second notice.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAmain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314, or send email to *splimpto@nsf.gov,* or by telephone to 703–292–7556. 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: NSF may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to the points of contact in the **FOR FURTHER INFORMATION CONTACT** section. Request for public comment was previously published March 13, 2024 at 89 FR 18442.

Title of Collection: Grantee Reporting Requirements for NSF SBIR/STTR Program.

OMB Number: 3145–0252.

Type of Request: Reinstatement and request for Office of Management and Budget (OMB) approval of an information collection.

Abstract:

Proposed Project:

This request is for reinstating interim reporting requirements for the NSF Small Business Innovation Research (SBIR)/Small Business Technology Transfer Research (STTR) programs.

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 (with an optional Phase IIB as matching supplements). SBIR/STTR 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, building on the feasibility project undertaken in Phase I, and accelerate the Phase I project to the commercialization stage and enhance the overall strength of the commercial potential. As such, Phase II SBIR/STTR awards have a longer expected period of performance of 24 months.

The NSF SBIR/STTR programs request approval from OMB on the reinstatement of the NSF SBIR/STTR Phase II interim/progress report data collection.

The interim/progress report will be required every six months for the life of the Phase II award. The report collects information on the technical progress of the funded NSF work, which allows managing Program Directors to monitor the project and ensure that the award is in good standing.

The report is divided into 6 sections: (1) Basic Reporting Data, (2) Level of Effort, (3) SBIR-wide Certifications, (4) Cooperative Agreement (NSF-specific

Certifications), (5) Technical Narratives, and (6) Project Milestones.

The kinds of data collected from the report include name of the startup company, information on the principal investigator (PI) (name, email address, and phone number), the number of full-time equivalent (FTE) employees working at the startup, amount of funding received during the award period. In addition, information pertaining to company officers and key personnel, their corresponding ownership status, and their levels of efforts provided to the startups are also requested. Collectively, these data will enable the managing Program Directors to (1) evaluate a given company's business structure, (2) ascertain the level of commitment of the PI(s), co-PI(s), and key personnel to the startup venture, and (3) identify conflicts of interests (if any), as part of the due diligence process that the programs undertake to verify that there are no fraudulent or inappropriate business practices.

The report also asks about: inputs (*i.e.,* project expenditures, efforts exerted by key personnel), outputs (*i.e.,* R&D activities, technical progresses), outcomes (*i.e.,* research milestones, fundraising activities), and impacts (*i.e.,* technical and/or commercial successes).

Finally, the report also requests: (1) a discussion of progresses highlighting key technical and commercial activity/results during the reporting period, (2) compliance requirements checklists from the Small Business Administration (SBA) and NSF, and (3) a Gantt chart describing the project status, as well as task assignments to key personnel in the project.

Use of the Information: The data collected will be used primarily for award monitoring. The data could also be used for congressional requests, inquiries from the NSF's Office of the Inspector General, supporting evidence of litigations, auditing, and other legal investigations, NSF internal reports, and program evaluations, if necessary.

Estimate of Burden: The estimated number of respondents is: 410. Average time to complete the interim report: 18 hours. The estimated total burden hours: 7,380 hours per year.

Respondents: The respondents are either PIs or Co-PIs listed on the NSF SBIR/STTR Proposals, Founders, and/or Co-founders of the startups funded by the NSF SBIR/STTR programs.

Dated: May 14, 2024.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2024–10892 Filed 5–16–24; 8:45 am]

BILLING CODE 7555–01–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2024–293; Order No. 7100]

Competitive Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is recognizing a recent filing by the Postal Service of specific rates for its Inbound Letter Post Small Packets and Bulky Letters product effective January 1, 2025. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* May 20, 2024.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

On May 10, 2024, the Postal Service filed a notice of rates not of general applicability for Inbound Letter Post Small Packets and Bulky Letters (Inbound E-format Letter Post) effective January 1, 2025.[1] The Postal Service requests that the Commission favorably review the proposed prices so that the Postal Service may submit the prices to the Universal Postal Union (UPU) before the June 1, 2024 deadline. Notice at 8.

II. Contents of Filing

In its Notice, the Postal Service proposes new prices for the Inbound Letter Post Small Packets and Bulky Letters product. *Id.* at 3. Under the UPU Convention, by June 1, 2024, the Postal Service may submit self-declared rates for Inbound Letter Post Small Packets and Bulky Letters to the UPU International Bureau (IB) that would take effect on January 1, 2025.[2] The Postal Service states that the proposed prices comply with 39 U.S.C. 3633. Notice at 8.

To support its proposed Inbound Letter Post Small Packets and Bulky Letters prices, the Postal Service filed the proposed prices, a copy of the certification required under 39 CFR 3035.105(c)(2), and a redacted copy of Governors' Decision No. 19–1. *Id.* at 6; *see id.* Attachments 2–4. The Postal Service also filed redacted financial workpapers. Notice at 6. In addition, the Postal Service filed an unredacted copy of Governors' Decision No. 19–1, the unredacted new prices, and unredacted financial information under seal. *Id.* The Postal Service also provided an application for non-public treatment of materials filed under seal filed pursuant to 39 CFR part 3011. *Id.; see id.* Attachment 1.

III. Administrative Actions

The Commission establishes Docket No. CP2024–293 for consideration of matters raised by the Notice and appoints Samuel Koroma to serve as Public Representative in this docket. The Commission invites comments on whether the Postal Service's filing is consistent with 39 U.S.C. 3632 and 3633 and 39 CFR 3035.105 and .107. Comments are due no later than May 20, 2024. The public portions of the filing can be accessed via the Commission's website (*http://www.prc.gov*).

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. CP2024–293 for consideration of the matters raised by the Postal Service's Notice.

2. Comments are due no later than May 20, 2024.

3. Pursuant to 39 U.S.C. 505, Samuel Koroma will serve as an officer of the Commission (Public Representative) to represent the interests of the general public in these dockets.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

[1] Notice of the United States Postal Service of Rates Not of General Applicability for Inbound E-Format Letter Post, and Application for Non-Public Treatment, May 10, 2024, at 1 (Notice).

[2] *Id.;* Universal Postal Convention (UPU Convention) Article 29.1. The UPU Convention is available at *https://www.upu.int/UPU/media/upu/files/aboutUpu/acts/03-actsConventionAndFinalProtocol/conventionAndFinalProtocolAdoptedAtAbidjanEn.pdf.*

By the Commission.

Erica A. Barker,

Secretary.

[FR Doc. 2024–10809 Filed 5–16–24; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2020–201; MC2024–291 and CP2024–299; MC2024–292 and CP2024–300; MC2024–293 and CP2024–301; MC2024–294 and CP2024–302]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* May 21, 2024.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the Market Dominant or the Competitive product list, or the modification of an existing product currently appearing on the Market Dominant or the Competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern Market Dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern Competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* CP2020–201; *Filing Title:* Notice of the United States Posal Service of Fling Modification Three to International Priority Airmail, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service with Reseller Contract 4 Negotiated Service Agreement; *Filing Acceptance Date:* May 13, 2024; *Filing Authority:* 39 CFR 3035.105; *Public Representative:* Katalin K. Clendenin; *Comments Due:* May 21, 2024.

2. *Docket No(s).:* MC2024–291 and CP2024–299; *Filing Title:* USPS Request to Add International Priority Airmail, Commercial ePacket, Priority Mail Express International & Priority Mail International Contract 5 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* May 13, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Jennaca D. Upperman; *Comments Due:* May 21, 2024.

3. *Docket No(s).:* MC2024–292 and CP2024–300; *Filing Title:* USPS Request to Add International Priority Airmail, Commercial ePacket, Priority Mail Express International & Priority Mail International Contract 6 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* May 13, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Jennaca D. Upperman; *Comments Due:* May 21, 2024.

4. *Docket No(s).:* MC2024–293 and CP2024–301; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 257 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* May 13, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* May 21, 2024.

5. *Docket No(s).:* MC2024–294 and CP2024–302; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 258 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* May 13, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Jennaca D. Upperman; *Comments Due:* May 21, 2024.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2024–10901 Filed 5–16–24; 8:45 am]

BILLING CODE 7710–FW–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

POSTAL REGULATORY COMMISSION

[Docket No. CP2024–295; Order No. 7101]

Competitive Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is recognizing a recently filed Postal Service document with the Commission concerning changes in rates of general applicability for Competitive products. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* June 3, 2024.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

On May 10, 2024, the Postal Service filed notice with the Commission concerning changes in rates of general applicability for Competitive products.[1] The Postal Service represents that, as required by 39 CFR 3035.102(b) and 39 CFR 3035.104(b), the Notice includes the Governors' Decision establishing the changes, including an explanation and justification for the changes, and certification of the vote. Notice at 1. The changes are scheduled to take effect on July 14, 2024. *Id.*

Attached to the Notice is Governors' Decision No. 24–3, which states the new prices are in accordance with 39 U.S.C. 3632 and 3633 and 39 CFR 3035.102–.104.[2] The Governors' Decision provides an analysis of the Competitive products' price changes intended to demonstrate that the changes comply with 39 U.S.C. 3633 and 39 CFR part 3035. Governors' Decision No. 24–3 at 1–2. The Attachment to the Governors' Decision No. 24–3 sets forth the price changes and includes draft Mail Classification Schedule (MCS) language for the impacted Competitive products of general applicability. *See* Notice at 1; Governor's Decision No. 24–3 at 1.

In addition, the Notice includes a non-public annex showing FY 2025 projected volumes, revenues, attributable costs, contribution, and cost coverage for each product. *See* Notice at 1. The Postal Service also filed supporting forecast data and price adjustment calculations for each affected product as required by Order No. 1062. *Id.*

The Notice also includes an application for non-public treatment of the unredacted version of the annex to the Governors' Decision, as well as the supporting materials for the data. *Id.*

II. Summary of Changes

The Postal Service proposes price changes for the Parcel Select product and states that ''[n]o other competitive product prices are changing for July 2024.'' [3] The proposed changes are designed to ''better align'' the Parcel Select product and pricing strategies with the Postal Service's operating model and goals. *Id.* More specifically, the Postal Service ''no longer intends to incentivize parties to aggregate mail volume from multiple shippers and bring such volume directly to the destination delivery unit (DDU).'' *Id.*

Accordingly, on average, Parcel Select prices are proposed to increase 25.0 percent. *Id.* For DDU entered parcels, the average price increase will be 43.4 percent, which, as the Postal Service states, will ''promote better utilization of network processing and transportation capacity by realigning rate relationships across entry points.'' *Id.* For destination section center facility (DSCF) entered parcels, the average price increase will be 8.6 percent. *Id.* For destination network distribution center (DNDC) entered parcels, the average price increase will be 18.6 percent. For USPS Connect Local pieces, the average price increase will be 15.9 percent, aiming to align with DDU prices. *Id.* Finally, for destination hub (Dhub) entered parcels, the average price increase will be 0.0 percent. *Id.*

III. Initial Administrative Actions

The Commission establishes Docket No. CP2024–295 to consider the Postal Service's Notice. Interested persons may express views and offer comments on whether the planned changes are consistent with 39 U.S.C. 3632, 3633, and 3642, 39 CFR part 3035, and 39 CFR 3040 subparts B and E. Comments are due June 3, 2024. For specific details of the planned price changes, interested persons are encouraged to review the Notice, which is available on the Commission's website at *www.prc.gov.*

Pursuant to 39 U.S.C. 505, Samuel Robinson is appointed to serve as Public Representative to represent the interests of the general public in this docket.

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. CP2024–295 to provide interested persons an opportunity to express views and offer comments on whether the planned changes are consistent with 39 U.S.C. 3632, 3633, and 3642, 39 CFR part 3035, and 39 CFR 3040 subparts B and E.

2. Comments are due June 3, 2024.

3. Pursuant to 39 U.S.C. 505, the Commission appoints Samuel Robinson to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this docket.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Erica A. Barker,

Secretary.

[FR Doc. 2024–10810 Filed 5–16–24; 8:45 am]

BILLING CODE 7710–FW–P

[1] USPS Notice of Changes in Rates of General Applicability for Competitive Products, May 10, 2024 (Notice). Pursuant to 39 U.S.C. 3632(b)(2), the Postal Service is obligated to publish the Governors' Decision and record of proceedings in the **Federal Register** at least 30 days before the effective date of the new rates.

[2] Notice, Decision of the Governors of the United States Postal Service on Changes in Rates of General Applicability for Competitive Products (Governors' Decision No. 24–3), at 2 (Governors' Decision No. 24–3).

[3] *Id.* at 2. There are no proposed price changes associated with any other Competitive product and no proposed classification changes in the instant proceeding. *Id.*

POSTAL SERVICE

Change in Rates of General Applicability for Competitive Products

AGENCY: Postal Service™.

ACTION: Notice of a change in rates of general applicability for competitive products.

SUMMARY: This notice sets forth changes in rates and classifications of general applicability for competitive products.

DATES: The rate change is effective July 14, 2024.

FOR FURTHER INFORMATION CONTACT: Elizabeth Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: On May 9, 2024, pursuant to their authority under 39 U.S.C. 3632, the Governors of the Postal Service established price changes for competitive products. The Governors' Decision and the record of proceedings in connection with such decision are reprinted below in accordance with section 3632(b)(2). Mail Classification Schedule language containing the new prices can be found at *www.prc.gov.*

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

Decision of the Governors of the United States Postal Service on Changes in Rates of General Applicability for Competitive Products (Governors' Decision No. 24–3)

May 9, 2024

Statement of Explanation and Justification

Pursuant to authority under section 3632 of title 39, as amended by the Postal Accountability and Enhancement Act of 2006 (''PAEA''), we establish price changes of general applicability for the Postal Service's shipping services (competitive products), specifically, Parcel Select. The changes are described generally below, with a detailed description of the changes in the Postal Service's associated draft Mail Classification Schedule change document. That document contains the

draft Mail Classification Schedule sections with new prices displayed in the price charts.

The Parcel Select price changes for July 2024 are designed to better align the Postal Service's product and pricing strategies with its operating model and goals. In order to more effectively utilize the postal processing and transportation network and realize enhanced economies, the Postal Service no longer intends to incent parties to aggregate mail volume from multiple shippers and to bring such volume directly to the destination delivery unit.

Accordingly, Parcel Select prices as a whole will increase 25.0 percent on average in July 2024. For destination delivery unit (DDU) entered parcels, the average price increase is 43.4 percent. These aggressive price changes for DDU promote full utilization of network processing and transportation capacity to achieve lower unit costs by realigning rate relationships across entry points. For destination hub (Dhub) entered parcels, the average price increase is 0.0 percent. For destination sectional center facility (DSCF) entered parcels, the average price increase is 8.6 percent. For destination network distribution center (DNDC) parcels, the average price increase is 18.6 percent. Prices for USPS Connect Local will increase 15.9 percent on average, in order to align with the DDU prices. No other price changes to the Parcel Select product, or any other competitive products, are established with this Decision.

As shown in the nonpublic annex being filed under seal herewith, the changes we establish should enable each competitive product to cover its attributable costs (39 U.S.C. 3633(a)(2)) and should result in competitive products as a whole complying with 39 U.S.C. 3633(a)(3), which, as implemented by 39 CFR 3035.107(c), requires competitive products collectively to contribute a minimum of 9.9 percent to the Postal Service's institutional costs. Accordingly, no issue of subsidization of competitive products by market dominant products should arise (39 U.S.C. 3633(a)(1)). We therefore find that the new prices and classification changes are in accordance with 39 U.S.C. 3632–3633 and 39 CFR 3035.102 and 104.

Order

The changes in prices set forth herein shall be effective at 12:01 a.m. on July 14, 2024. We direct the Secretary to have this decision published in the **Federal Register** in accordance with 39 U.S.C. 3632(b)(2) and direct management to file with the Postal Regulatory Commission appropriate notice of these changes.

By The Governors:
Roman Martinez IV
Chairman, Board of Governors.

UNITED STATES POSTAL SERVICE OFFICE OF THE BOARD OF GOVERNORS

Certification of Governors' Vote on Governors' Decision NO. 24–3

Consistent with 39 U.S.C. 3632(a), I hereby certify that, on May 9, 2024, the Governors voted on adopting Governors' Decision No. 24–3, and that a majority of the Governors then holding office voted in favor of that Decision.

Date: May 9, 2024.
Michael J. Elston,
Secretary of the Board of Governors.
[FR Doc. 2024–10907 Filed 5–16–24; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

International Product Change—International Priority Airmail, Commercial ePacket, Priority Mail Express International & Priority Mail International Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add an International Priority Airmail, Commercial ePacket, Priority Mail Express International & Priority Mail International contract to the list of Negotiated Service Agreements in the Competitive Product List in the Mail Classification Schedule.

DATES: Date of notice: May 17, 2024.

FOR FURTHER INFORMATION CONTACT: Christopher C. Meyerson, (202) 268–7820.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on May 10, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add International Priority Airmail, Commercial ePacket, Priority Mail Express International & Priority Mail International Contract 3 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–286 and CP2024–292.

Colleen Hibbert-Kapler,
Attorney, Ethics and Legal Compliance.
[FR Doc. 2024–10791 Filed 5–16–24; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

International Product Change—International Priority Airmail, Commercial ePacket, Priority Mail Express International & Priority Mail International Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add an International Priority Airmail, Commercial ePacket, Priority Mail Express International & Priority Mail International contract to the list of Negotiated Service Agreements in the Competitive Product List in the Mail Classification Schedule.

DATES: *Date of notice:* May 17, 2024.

FOR FURTHER INFORMATION CONTACT: Christopher C. Meyerson, (202) 268–7820.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on May 13, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add International Priority Airmail, Commercial ePacket, Priority Mail Express International & Priority Mail International Contract 6 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–292 and CP2024–300.

Colleen Hibbert-Kapler,
Attorney, Ethics and Legal Compliance.
[FR Doc. 2024–10890 Filed 5–16–24; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

International Product Change—International Priority Airmail, Commercial ePacket, Priority Mail Express International & Priority Mail International Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add an International Priority Airmail, Commercial ePacket, Priority Mail Express International & Priority Mail International contract to the list of Negotiated Service Agreements in the Competitive Product List in the Mail Classification Schedule.

DATES: Date of notice: May 17, 2024.

FOR FURTHER INFORMATION CONTACT: Christopher C. Meyerson, (202) 268–7820.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on May 9, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add International Priority Airmail, Commercial ePacket, Priority Mail Express International & Priority Mail International Contract 1 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–282 and CP2024–288.

Christopher Doyle,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2024–10839 Filed 5–16–24; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

International Product Change—International Priority Airmail, Commercial ePacket, Priority Mail Express International & Priority Mail International Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add an International Priority Airmail, Commercial ePacket, Priority Mail Express International & Priority Mail International contract to the list of Negotiated Service Agreements in the Competitive Product List in the Mail Classification Schedule.

DATES: Date of notice: May 17, 2024.

FOR FURTHER INFORMATION CONTACT: Christopher C. Meyerson, (202) 268–7820.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on May 10, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add International Priority Airmail, Commercial ePacket, Priority Mail Express International & Priority Mail International Contract 4 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–290 and CP2024–298.

Christopher Doyle,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2024–10840 Filed 5–16–24; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

International Product Change—International Priority Airmail, Commercial ePacket, Priority Mail Express International & Priority Mail International Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add an International Priority Airmail, Commercial ePacket, Priority Mail Express International & Priority Mail International contract to the list of Negotiated Service Agreements in the Competitive Product List in the Mail Classification Schedule.

DATES: Date of notice: May 17, 2024.

FOR FURTHER INFORMATION CONTACT: Christopher C. Meyerson, (202) 268–7820.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on May 13, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add International Priority Airmail, Commercial ePacket, Priority Mail Express International & Priority Mail International Contract 5 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–291 and CP2024–299.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2024–10909 Filed 5–16–24; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

International Product Change—International Priority Airmail, Commercial ePacket, Priority Mail Express International & Priority Mail International Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add an International Priority Airmail, Commercial ePacket, Priority Mail Express International & Priority Mail International contract to the list of Negotiated Service Agreements in the Competitive Product List in the Mail Classification Schedule.

DATES: *Date of notice:* May 17, 2024.

FOR FURTHER INFORMATION CONTACT: Christopher C. Meyerson, (202) 268–7820.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on May 10, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add International Priority Airmail, Commercial ePacket, Priority Mail Express International & Priority Mail International Contract 2 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–285 and CP2024–291.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2024–10906 Filed 5–16–24; 8:45 am]

BILLING CODE 7710–12–P

RAILROAD RETIREMENT BOARD

Actuarial Advisory Committee With Respect to the Railroad Retirement Account; Notice of Public Meeting

Notice is hereby given in accordance with Public Law 92–463 that the Actuarial Advisory Committee will hold a meeting on June 4, 2024, at 12 p.m. (central daylight time) at the office of the Chief Actuary of the U.S. Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092, on the conduct of the 29th Actuarial Valuation of the Railroad Retirement System. The agenda for this meeting will include a discussion of the results and presentation of the 29th Actuarial Valuation. The text and tables that constitute the Valuation will have been prepared in draft form for review by the Committee. It is expected that this will be the last meeting of the Committee before publication of the Valuation.

The meeting will be open to the public. Persons wishing to submit written statements or make oral presentations should address their communications or notices to Patricia Pruitt (*Patricia.Pruitt@rrb.gov*).

Dated: May 14, 2024.

Sarah Kreydich,

Administrative Specialist.

[FR Doc. 2024–10859 Filed 5–16–24; 8:45 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100120; File No. SR–ISE–2024–16]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Fees for Connectivity and Co-Location Services

May 13, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 29, 2024, Nasdaq ISE, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's fees for connectivity and co-location services, as described further below.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/ise/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's fees relating to connectivity and co-location services.[3] Specifically, the Exchange proposes to raise its fees for connectivity and co-location services in General 8 as well as certain fees related to its Testing Facilities in Options 7, Section 8 by 5.5%, with certain exceptions.

General 8, Section 1 includes the Exchange's fees that relate to connectivity, including fees for cabinets, external telco/inter-cabinet connectivity fees, fees for connectivity to the Exchange, fees for connectivity to third party services, fees for market data connectivity, fees for cabinet power install, and fees for additional charges and services. General 8, Section 2 includes the Exchange's fees for direct connectivity services, including fees for direct circuit connection to the Exchange, fees for direct circuit connection to third party services, and fees for point of presence connectivity. With the exception of the Exchange's GPS Antenna fees and the Cabinet Proximity Option Fee for cabinets with power density >10kW,[4] the Exchange proposes to increase its fees throughout General 8 by 5.5%.

In addition to increasing fees in General 8, the Exchange also proposes to increase certain fees in Options 7, Section 8, which relate to the Testing Facility. Options 7, Section 8(I) provides that subscribers to the Testing Facility located in Carteret, New Jersey shall pay a fee of $1,000 per hand-off, per month for connection to the Testing Facility. The hand-off fee includes either a 1Gb or 10Gb switch port and a cross connect to the Testing Facility. In addition, Options 7, Section 8(I) provides that subscribers shall also pay a one-time installation fee of $1,000 per hand-off. The Exchange proposes to increase these aforementioned fees by 5.5% to require that subscribers to the Testing Facility shall pay a fee of $1,055 per hand-off, per month for connection to the Testing Facility and a one-time installation fee of $1,055 per hand-off.

The proposed increases in fees would enable the Exchange to maintain and improve its market technology and services. The Exchange has not increased any of the fees included in the proposal since 2017.[5] However, since 2017, there has been notable inflation. Between 2017 and 2024, the dollar had an average inflation rate of 3.34% per year, producing a cumulative price increase of 25.82%.[6] Notwithstanding inflation, the Exchange historically has not increased its fees every year.[7] The proposed fees represent a 5.5% increase from the current fees, which is far below inflation since 2017, which exceeded 25%. In addition to being far below the cumulative inflation rate since 2017, the Exchange also believes that the proposed 5.5% increase is reasonable because it is comparable to recent inflation rates for one-year periods. For example, in 2023, the inflation rate was 4.12% and in 2022, the inflation rate was 8%.[8] The Exchange is sensitive to the sticker shock that would occur if the Exchange raised its fees by more than 25% and therefore proposes a more modest increase, similar to that of inflation in recent one-year periods.

The Exchange believes that it is reasonable to increase its fees to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2017. The Exchange notes that this inflationary effect is a general phenomenon that is independent of any change in the Exchange's costs in providing its goods and services. The Exchange believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects. The Exchange notes that other exchanges have filed for comparable or higher increases in certain connectivity-related fees, based in part on similar rationale.[9]

In addition, the Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange initially filed the proposed pricing change on March 1, 2024 (SR–ISE–2024–09). The instant filing replaces SR–ISE–2024–09, which was withdrawn on April 29, 2024.

[4] The Exchange proposes to exclude the GPS Antenna fees from the proposed fee increase because, unlike the other fees in General 8, the Exchange recently increased its GPS Antenna fees. *See* Securities Exchange Act Release No. 34–99131 (December 11, 2023), 88 FR 86979 (December 15, 2023) (SR–ISE–2023–33). The Exchange also proposes to exclude the Cabinet Proximity Option Fee for cabinets with power density >10kW from the proposed fee increase because the Exchange recently established such fee. *See* Securities Exchange Act Release No. 34–99799 (March 20, 2024), 89 FR 21162 (March 26, 2024) (SR–ISE–2024–13).

[5] *See* Securities Exchange Act Release No. 34–81903 (October 19, 2017), 82 FR 49450 (October 25, 2017) (SR–ISE–2017–91).

[6] *See https://www.officialdata.org/us/inflation/2017?amount=1* (Last updated February 27, 2024).

[7] Unregulated competitors providing connectivity and colocation services often have annual price increases written into their agreements with customers to account for inflation and rising costs.

[8] *See https://www.officialdata.org/us/inflation/2022?endYear=2023&amount=1.*

[9] *See, e.g.,* Securities Exchange Act Release No. 34–100004 (April 22, 2024), 89 FR 32465 (April 26, 2024) (SR–CboeBYX–2024–012).

enhancements include refreshing hardware and expanding the Exchange's existing co-location facility to offer customers additional space and power. These investments, and the value they provide to customers, far exceed the amount of the proposed price increases. It is reasonable and consistent with the Act for the Commission to allow the Exchange to recoup these investments by charging fees, lest the Commission will disincentivize the Exchange to make similar investments in the future—a result that would be detrimental to the Exchange's competitiveness as well as the interests of market participants and investors.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[11] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

This belief is based on a couple factors. First, the current fees do not properly reflect the value of the services and products, as fees for the services and products in question have been static in nominal terms, and therefore falling in real terms due to inflation. Second, exchange fees are constrained by the fact that market participants can choose among 17 different venues for options trading, and therefore no single venue can charge excessive fees for its products without losing customers and market share.

Real Exchange Fees Have Fallen

As explained above, the Exchange has not increased any of the fees included in the proposal since 2017. This means that such fees have fallen in real terms due to inflation, which has been notable. Between 2017 and 2024, the dollar had an average inflation rate of 3.34% per year, producing a cumulative price increase of 25.82%.[12] Notwithstanding inflation, the Exchange historically has not increased its fees every year.[13] As noted above, the Exchange has not increased the fees in this proposal for over 6 years. Accordingly, the Exchange believes that the proposed fees are reasonable as they represent a 5.5% increase from the current fees, which is far below inflation since 2017, which exceeded 25%. In addition to being far below the inflation rate since 2017, the Exchange also believes that the proposed 5.5% increase is reasonable because it is comparable to recent inflation rates for one-year periods. For example, in 2023, the inflation rate was 4.12% and in 2022, the inflation rate was 8%.[14] The Exchange is sensitive to the sticker shock that would occur if the Exchange raised its fees by more than 25% and therefore proposes a more modest increase, similar to that of inflation in recent one-year periods.

The Exchange believes that it is reasonable to increase its fees to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2017. The Exchange notes that this inflationary effect is a general phenomenon that is independent of any change in the Exchange's costs in providing its goods and services. The Exchange believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects.

In addition, the Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding the Exchange's existing co-location facility to offer customers additional space and power. Again, these investments, and the value they provide to customers, far exceed the amount of the proposed price increases. It is reasonable and consistent with the Act for the Commission to allow the Exchange to recoup these investments by charging fees, lest the Commission will disincentivize the Exchange to make similar investments in the future—a result that would be detrimental to the Exchange's competitiveness as well as the interests of market participants and investors.

Customers Have a Choice in Trading Venue

Customers face many choices in where to trade options. Market participants will continue to choose trading venues and the method of connectivity based on their specific needs. No broker-dealer is required to become a Member of the Exchange. There is no regulatory requirement that any market participant connect to any one exchange, nor that any market participant connect at a particular connection speed or act in a particular capacity on the Exchange, or trade any particular product offered on an exchange. Moreover, membership is not a requirement to participate on the Exchange. Indeed, the Exchange is unaware of any one exchange whose membership includes every registered broker-dealer. The Exchange also believes substitutable products and services are available to market participants, including, among other things, other options exchanges that a market participant may connect to in lieu of the Exchange, indirect connectivity to the Exchange via a third-party reseller of connectivity, and/or trading of options products within markets which do not require connectivity to the Exchange, such as the Over-the-Counter (OTC) markets.

There are currently 17 exchanges offering options trading services. No single options exchange trades more than 14% of the options market by volume and only one of the 17 options exchanges has a market share over 10 percent.[15] This broad dispersion of market share demonstrates that market participants can and do exercise choice in trading venues. Further, low barriers to entry mean that new exchanges may rapidly enter the market and offer additional substitute platforms to further compete with the Exchange and the products it offers.

As such, the Exchange must set its fees, including its fees for connectivity and co-location services and products, competitively. If not, customers may move to other venues or reduce use of the Exchange's services. ''If competitive forces are operative, the self-interest of the exchanges themselves will work powerfully to constrain unreasonable or unfair behavior.'' [16] Accordingly, ''the existence of significant competition provides a substantial basis for finding that the terms of an exchange's fee proposal are equitable, fair, reasonable, and not unreasonably or unfairly discriminatory.'' [17] Disincentivizing market participants from purchasing Exchange connectivity would only serve

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4) and (5).

[12] *See https://www.officialdata.org/us/inflation/2017?amount=1* (Last updated February 27, 2024).

[13] As noted above, unregulated competitors providing connectivity and colocation services often have annual price increases written into their agreements with customers to account for inflation and rising costs.

[14] *See https://www.officialdata.org/us/inflation/2022?endYear=2023&amount=1.*

[15] *See* Nasdaq, Options Market Statistics (Last updated January 11, 2024), available at *https://www.nasdaqtrader.com/Trader.aspx?id=OptionsVolumeSummary.*

[16] *See* Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770 (December 9, 2008) (SR–NYSEArca–2006–21).

[17] *Id.*

to discourage participation on the Exchange, which ultimately does not benefit the Exchange. Moreover, if the Exchange charges excessive fees, it may stand to lose not only connectivity revenues but also other revenues, including revenues associated with the execution of orders.

In summary, the proposal represents an equitable allocation of reasonable dues, fees and other charges because Exchange fees have fallen in real terms and customers have a choice in trading venue and will exercise that choice and trade at another venue if exchange fees are not set competitively.

No Unfair Discrimination

The Exchange believes that the proposed fee changes are not unfairly discriminatory because the fees are assessed uniformly across all market participants that voluntarily subscribe to or purchase connectivity and co-location services or products, which are available to all customers.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Nothing in the proposal burdens inter-market competition (the competition among self-regulatory organizations) because approval of the proposal does not impose any burden on the ability of other exchanges to compete. The Exchange operates in a highly competitive market in which market participants can determine whether or not to connect to the Exchange based on the value received compared to the cost of doing so. Indeed, market participants have numerous alternative exchanges that they may participate on and direct their order flow, as well as off-exchange venues, where competitive products are available for trading.

Nothing in the proposal burdens intra-market competition (the competition among consumers) because the Exchange's connectivity and co-location services are available to any customer under the same fee schedule as any other customer, and any market participant that wishes to purchase such services can do so on a non-discriminatory basis.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[18] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–ISE–2024–16 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–ISE–2024–16. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–ISE–2024–16 and should be submitted on or before June 7, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–10815 Filed 5–16–24; 8:45 am]

BILLING CODE 8011–01–P

[18] 15 U.S.C. 78s(b)(3)(A)(ii).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100119; File No. SR–Phlx–2024–19]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend its Fees for Connectivity and Co-location Services

May 13, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 29, 2024, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's fees for connectivity and co-location services, as described further below.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/phlx/rules,* at the principal

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's fees relating to connectivity and co-location services.[3] Specifically, the Exchange proposes to raise its fees for connectivity and co-location services in General 8 as well as certain fees related to its Testing Facilities in Equity 7, Section 3 by 5.5%, with certain exceptions.

General 8, Section 1 includes the Exchange's fees that relate to connectivity, including fees for cabinets, external telco/inter-cabinet connectivity fees, fees for connectivity to the Exchange, fees for connectivity to third party services, fees for market data connectivity, fees for cabinet power install, and fees for additional charges and services. General 8, Section 2 includes the Exchange's fees for direct connectivity services, including fees for direct circuit connection to the Exchange, fees for direct circuit connection to third party services, and fees for point of presence connectivity. With the exception of the Exchange's GPS Antenna fees and the Cabinet Proximity Option Fee for cabinets with power density >10kW,[4] the Exchange proposes to increase its fees throughout General 8 by 5.5%.

In addition to increasing fees in General 8, the Exchange also proposes to increase certain fees in Equity 7, Section 3, which relate to the Testing Facility. Equity 7, Section 3 provides that subscribers to the Testing Facility located in Carteret, New Jersey shall pay a fee of $1,000 per hand-off, per month for connection to the Testing Facility. The hand-off fee includes either a 1Gb or 10Gb switch port and a cross connect to the Testing Facility. In addition, Equity 7, Section 3 provides that subscribers shall also pay a one-time installation fee of $1,000 per hand-off. The Exchange proposes to increase these aforementioned fees by 5.5% to require that subscribers to the Testing Facility shall pay a fee of $1,055 per hand-off, per month for connection to the Testing Facility and a one-time installation fee of $1,055 per hand-off.

The proposed increases in fees would enable the Exchange to maintain and improve its market technology and services. With the exception of fees that were established as part of a new service in 2017 (and have remained unchanged since their adoption), the Exchange has not increased any of the fees included in the proposal since 2015, and many of the fees date back to between 2010 and 2014. However, since 2015, there has been notable inflation. Between 2015 and 2024, the dollar had an average inflation rate of 2.97% per year, producing a cumulative price increase of 30.12%.[5] Notwithstanding inflation, the Exchange historically has not increased its fees every year.[6] The proposed fees represent a 5.5% increase from the current fees, which is far below inflation since 2015, which exceeded 30%.[7] In addition to being far below the cumulative inflation rate since 2015, the Exchange also believes that the proposed 5.5% increase is reasonable because it is comparable to recent inflation rates for one-year periods. For example, in 2023, the inflation rate was 4.12% and in 2022, the inflation rate was 8%.[8] The Exchange is sensitive to the sticker shock that would occur if the Exchange raised its fees by more than 30% and therefore proposes a more modest increase, similar to that of inflation in recent one-year periods.

The Exchange believes that it is reasonable to increase its fees to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2015. The Exchange notes that this inflationary effect is a general phenomenon that is independent of any change in the Exchange's costs in providing its goods and services. The Exchange believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects. The Exchange notes that other exchanges have filed for comparable or higher increases in certain connectivity-related fees, based in part on similar rationale.[9]

In addition, the Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding the Exchange's existing co-location facility to offer customers additional space and power. These investments, and the value they provide to customers, far exceed the amount of the proposed price increases. It is reasonable and consistent with the Act for the Commission to allow the Exchange to recoup these investments by charging fees, lest the Commission will disincentivize the Exchange to make similar investments in the future—a result that would be detrimental to the Exchange's competitiveness as well as the interests of market participants and investors.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[11] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

This belief is based on a couple factors. First, the current fees do not properly reflect the value of the services

[3] The Exchange initially filed the proposed pricing change on March 1, 2024 (SR–Phlx–2024–08). The instant filing replaces SR–Phlx–2024–08, which was withdrawn on April 29, 2024.

[4] The Exchange proposes to exclude the GPS Antenna fees from the proposed fee increase because, unlike the other fees in General 8, the Exchange recently increased its GPS Antenna fees. *See* Securities Exchange Act Release No. 34–99125 (December 8, 2023), 88 FR 86705 (December 14, 2023) (SR–Phlx–2023–53). The Exchange also proposes to exclude the Cabinet Proximity Option Fee for cabinets with power density >10kW from the proposed fee increase because the Exchange recently established such fee. *See* Securities Exchange Act Release No. 34–99797 (March 20, 2024), 89 FR 21148 (March 26, 2024) (SR–Phlx–2024–12).

[5] *See https://www.officialdata.org/us/inflation/2015?amount=1* (Last updated February 27, 2024).

[6] Unregulated competitors providing connectivity and colocation services often have annual price increases written into their agreements with customers to account for inflation and rising costs.

[7] Between 2017 and 2024, inflation exceeded 25%. *See https://www.officialdata.org/us/inflation/2017?amount=1* (Last updated February 27, 2024).

[8] *See https://www.officialdata.org/us/inflation/2022?endYear=2023&amount=1.*

[9] *See, e.g.,* Securities Exchange Act Release No. 34–100004 (April 22, 2024), 89 FR 32465 (April 26, 2024) (SR–CboeBYX–2024–012).

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4) and (5).

and products, as fees for the services and products in question have been static in nominal terms, and therefore falling in real terms due to inflation. Second, exchange fees are constrained by the fact that market participants can choose among 16 different venues for equities trading and 17 different venues for options trading, and therefore no single venue can charge excessive fees for its products without losing customers and market share.

Real Exchange Fees Have Fallen

As explained above, with the exception of fees that were established as part of a new service in 2017 (and have remained unchanged since their adoption), the Exchange has not increased any of the fees included in the proposal since 2015, and many of the fees date back to between 2010 and 2014. This means that such fees have fallen in real terms due to inflation, which has been notable. Between 2015 and 2024, the dollar had an average inflation rate of 2.97% per year, producing a cumulative price increase of 30.12%.[12] Notwithstanding inflation, the Exchange historically has not increased its fees every year.[13] As noted above, the Exchange has not increased the fees in this proposal for over 8 years (or in the case of services introduced in 2017, for over 6 years since the services were introduced). Accordingly, the Exchange believes that the proposed fees are reasonable as they represent a 5.5% increase from the current fees, which is far below inflation since 2015, which exceeded 30%.[14] In addition to being far below the inflation rate since 2015, the Exchange also believes that the proposed 5.5% increase is reasonable because it is comparable to recent inflation rates for one-year periods. For example, in 2023, the inflation rate was 4.12% and in 2022, the inflation rate was 8%.[15] The Exchange is sensitive to the sticker shock that would occur if the Exchange raised its fees by more than 30% and therefore proposes a more modest increase, similar to that of inflation in recent one-year periods.

The Exchange believes that it is reasonable to increase its fees to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2015. The Exchange notes that this inflationary effect is a general phenomenon that is independent of any change in the Exchange's costs in providing its goods and services. The Exchange believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects.

In addition, the Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding the Exchange's existing co-location facility to offer customers additional space and power. Again, these investments, and the value they provide to customers, far exceed the amount of the proposed price increases. It is reasonable and consistent with the Act for the Commission to allow the Exchange to recoup these investments by charging fees, lest the Commission will disincentivize the Exchange to make similar investments in the future—a result that would be detrimental to the Exchange's competitiveness as well as the interests of market participants and investors.

Customers Have a Choice in Trading Venue

Customers face many choices in where to trade both equities and options. Market participants will continue to choose trading venues and the method of connectivity based on their specific needs. No broker-dealer is required to become a Member of the Exchange. There is no regulatory requirement that any market participant connect to any one exchange, nor that any market participant connect at a particular connection speed or act in a particular capacity on the Exchange, or trade any particular product offered on an exchange. Moreover, membership is not a requirement to participate on the Exchange. Indeed, the Exchange is unaware of any one exchange whose membership includes every registered broker-dealer. The Exchange also believes substitutable products and services are available to market participants, including, among other things, other equities and options exchanges that a market participant may connect to in lieu of the Exchange, indirect connectivity to the Exchange via a third-party reseller of connectivity, and/or trading of equities or options products within markets which do not require connectivity to the Exchange, such as the Over-the-Counter (OTC) markets.

There are currently 16 registered equities exchanges that trade equities and 17 exchanges offering options trading services. No single equities exchange has more than 15% of the market share.[16] No single options exchange trades more than 14% of the options market by volume and only one of the 17 options exchanges has a market share over 10 percent.[17] This broad dispersion of market share demonstrates that market participants can and do exercise choice in trading venues. Further, low barriers to entry mean that new exchanges may rapidly enter the market and offer additional substitute platforms to further compete with the Exchange and the products it offers.

As such, the Exchange must set its fees, including its fees for connectivity and co-location services and products, competitively. If not, customers may move to other venues or reduce use of the Exchange's services. ''If competitive forces are operative, the self-interest of the exchanges themselves will work powerfully to constrain unreasonable or unfair behavior.'' [18] Accordingly, ''the existence of significant competition provides a substantial basis for finding that the terms of an exchange's fee proposal are equitable, fair, reasonable, and not unreasonably or unfairly discriminatory.'' [19] Disincentivizing market participants from purchasing Exchange connectivity would only serve to discourage participation on the Exchange, which ultimately does not benefit the Exchange. Moreover, if the Exchange charges excessive fees, it may stand to lose not only connectivity revenues but also other revenues, including revenues associated with the execution of orders.

In summary, the proposal represents an equitable allocation of reasonable dues, fees and other charges because Exchange fees have fallen in real terms and customers have a choice in trading venue and will exercise that choice and trade at another venue if exchange fees are not set competitively.

[12] *See https://www.officialdata.org/us/inflation/2015?amount=1* (Last updated February 27, 2024).

[13] As noted above, unregulated competitors providing connectivity and colocation services often have annual price increases written into their agreements with customers to account for inflation and rising costs.

[14] Between 2017 and 2024, inflation exceeded 25%. *See https://www.officialdata.org/us/inflation/2017?amount=1* (Last updated February 27, 2024).

[15] *See https://www.officialdata.org/us/inflation/2022?endYear=2023&amount=1.*

[16] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (Last updated January 11, 2024), available at *https://www.cboe.com/us/equities/market_statistics/.*

[17] *See* Nasdaq, Options Market Statistics (Last updated January 11, 2024), available at *https://www.nasdaqtrader.com/Trader.aspx?id=OptionsVolumeSummary.*

[18] *See* Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74,770 (December 9, 2008) (SR–NYSEArca–2006–21).

[19] *Id.*

No Unfair Discrimination

The Exchange believes that the proposed fee changes are not unfairly discriminatory because the fees are assessed uniformly across all market participants that voluntarily subscribe to or purchase connectivity and co-location services or products, which are available to all customers.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Nothing in the proposal burdens inter-market competition (the competition among self-regulatory organizations) because approval of the proposal does not impose any burden on the ability of other exchanges to compete. The Exchange operates in a highly competitive market in which market participants can determine whether or not to connect to the Exchange based on the value received compared to the cost of doing so. Indeed, market participants have numerous alternative exchanges that they may participate on and direct their order flow, as well as off-exchange venues, where competitive products are available for trading.

Nothing in the proposal burdens intra-market competition (the competition among consumers) because the Exchange's connectivity and co-location services are available to any customer under the same fee schedule as any other customer, and any market participant that wishes to purchase such services can do so on a non-discriminatory basis.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[20]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–Phlx–2024–19 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–Phlx–2024–19. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–Phlx–2024–19 and should be submitted on or before June 7, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–10814 Filed 5–16–24; 8:45 am]

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[20] 15 U.S.C. 78s(b)(3)(A)(ii).

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100118; File No. SR–GEMX–2024–09]

Self-Regulatory Organizations; Nasdaq GEMX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Fees for Connectivity and Co-Location Services

May 13, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 29, 2024, Nasdaq GEMX, LLC (''GEMX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's fees for connectivity and co-location services, as described further below.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/gemx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's fees relating to connectivity and co-location services.[3] Specifically, the Exchange proposes to raise its fees for connectivity and co-location services in General 8 as well as certain fees related to its Testing Facilities in Options 7, Section 6 by 5.5%, with certain exceptions.

General 8, Section 1 includes the Exchange's fees that relate to connectivity, including fees for cabinets, external telco/inter-cabinet connectivity fees, fees for connectivity to the Exchange, fees for connectivity to third party services, fees for market data connectivity, fees for cabinet power install, and fees for additional charges and services. General 8, Section 2 includes the Exchange's fees for direct connectivity services, including fees for direct circuit connection to the Exchange, fees for direct circuit connection to third party services, and fees for point of presence connectivity. With the exception of the Exchange's GPS Antenna fees and the Cabinet Proximity Option Fee for cabinets with power density >10kW,[4] the Exchange proposes to increase its fees throughout General 8 by 5.5%.

In addition to increasing fees in General 8, the Exchange also proposes to increase certain fees in Options 7, Section 6, which relate to the Testing Facility. Options 7, Section 6(H) provides that subscribers to the Testing Facility located in Carteret, New Jersey shall pay a fee of $1,000 per hand-off, per month for connection to the Testing Facility. The hand-off fee includes either a 1Gb or 10Gb switch port and a cross connect to the Testing Facility. In addition, Options 7, Section 6(H) provides that subscribers shall also pay a one-time installation fee of $1,000 per hand-off. The Exchange proposes to increase these aforementioned fees by 5.5% to require that subscribers to the Testing Facility shall pay a fee of $1,055 per hand-off, per month for connection to the Testing Facility and a one-time installation fee of $1,055 per hand-off.

The proposed increases in fees would enable the Exchange to maintain and improve its market technology and services. The Exchange has not increased any of the fees included in the proposal since 2017.[5] However, since 2017, there has been notable inflation. Between 2017 and 2024, the dollar had an average inflation rate of 3.34% per year, producing a cumulative price increase of 25.82%.[6] Notwithstanding inflation, the Exchange historically has not increased its fees every year.[7] The proposed fees represent a 5.5% increase from the current fees, which is far below inflation since 2017, which exceeded 25%. In addition to being far below the cumulative inflation rate since 2017, the Exchange also believes that the proposed 5.5% increase is reasonable because it is comparable to recent inflation rates for one-year periods. For example, in 2023, the inflation rate was 4.12% and in 2022, the inflation rate was 8%.[8] The Exchange is sensitive to the sticker shock that would occur if the Exchange raised its fees by more than 25% and therefore proposes a more modest increase, similar to that of inflation in recent one-year periods.

The Exchange believes that it is reasonable to increase its fees to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2017. The Exchange notes that this inflationary effect is a general phenomenon that is independent of any change in the Exchange's costs in providing its goods and services. The Exchange believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects. The Exchange notes that other exchanges have filed for comparable or higher increases in certain connectivity-related fees, based in part on similar rationale.[9]

In addition, the Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding the Exchange's existing co-location facility to offer customers additional space and power. These investments, and the value they provide to customers, far exceed the amount of the proposed price increases. It is reasonable and consistent with the Act for the Commission to allow the Exchange to recoup these investments by charging fees, lest the Commission will disincentivize the Exchange to make similar investments in the future—a result that would be detrimental to the Exchange's competitiveness as well as the interests of market participants and investors.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[11] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

This belief is based on a couple factors. First, the current fees do not properly reflect the value of the services and products, as fees for the services and products in question have been static in nominal terms, and therefore falling in real terms due to inflation. Second, exchange fees are constrained by the fact that market participants can choose among 17 different venues for options trading, and therefore no single venue can charge excessive fees for its products without losing customers and market share.

Real Exchange Fees Have Fallen

As explained above, the Exchange has not increased any of the fees included in the proposal since 2017. This means that such fees have fallen in real terms due to inflation, which has been notable. Between 2017 and 2024, the dollar had an average inflation rate of 3.34% per year, producing a cumulative

[3] The Exchange initially filed the proposed pricing change on March 1, 2024 (SR–GEMX–2024–05). The instant filing replaces SR–GEMX–2024–05, which was withdrawn on April 29, 2024.

[4] The Exchange proposes to exclude the GPS Antenna fees from the proposed fee increase because, unlike the other fees in General 8, the Exchange recently increased its GPS Antenna fees. *See* Securities Exchange Act Release No. 34–99129 (December 11, 2023), 88 FR 87017 (December 15, 2023) (SR–GEMX–2023–17). The Exchange also proposes to exclude the Cabinet Proximity Option Fee for cabinets with power density >10kW from the proposed fee increase because the Exchange recently established such fee. *See* Securities Exchange Act Release No. 34–99800 (March 20, 2024), 89 FR 21020 (March 26, 2024) (SR–GEMX–2024–08).

[5] *See* Securities Exchange Act Release No. 34–81902 (October 19, 2017), 82 FR 49453 (October 25, 2017) (SR–GEMX–2017–48).

[6] *See https://www.officialdata.org/us/inflation/2017?amount=1* (Last updated February 27, 2024).

[7] Unregulated competitors providing connectivity and colocation services often have annual price increases written into their agreements with customers to account for inflation and rising costs.

[8] *See https://www.officialdata.org/us/inflation/2022?endYear=2023&amount=1.*

[9] *See, e.g.,* Securities Exchange Act Release No. 34–100004 (April 22, 2024), 89 FR 32465 (April 26, 2024) (SR–CboeBYX–2024–012).

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4) and (5).

price increase of 25.82%.[12] Notwithstanding inflation, the Exchange historically has not increased its fees every year.[13] As noted above, the Exchange has not increased the fees in this proposal for over 6 years. Accordingly, the Exchange believes that the proposed fees are reasonable as they represent a 5.5% increase from the current fees, which is far below inflation since 2017, which exceeded 25%. In addition to being far below the inflation rate since 2017, the Exchange also believes that the proposed 5.5% increase is reasonable because it is comparable to recent inflation rates for one-year periods. For example, in 2023, the inflation rate was 4.12% and in 2022, the inflation rate was 8%.[14] The Exchange is sensitive to the sticker shock that would occur if the Exchange raised its fees by more than 25% and therefore proposes a more modest increase, similar to that of inflation in recent one-year periods.

The Exchange believes that it is reasonable to increase its fees to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2017. The Exchange notes that this inflationary effect is a general phenomenon that is independent of any change in the Exchange's costs in providing its goods and services. The Exchange believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects.

In addition, the Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding the Exchange's existing co-location facility to offer customers additional space and power. Again, these investments, and the value they provide to customers, far exceed the amount of the proposed price increases. It is reasonable and consistent with the Act for the Commission to allow the Exchange to recoup these investments by charging fees, lest the Commission will disincentivize the Exchange to make similar investments in the future—a result that would be detrimental to the Exchange's competitiveness as well as the interests of market participants and investors.

Customers Have a Choice in Trading Venue

Customers face many choices in where to trade options. Market participants will continue to choose trading venues and the method of connectivity based on their specific needs. No broker-dealer is required to become a Member of the Exchange. There is no regulatory requirement that any market participant connect to any one exchange, nor that any market participant connect at a particular connection speed or act in a particular capacity on the Exchange, or trade any particular product offered on an exchange. Moreover, membership is not a requirement to participate on the Exchange. Indeed, the Exchange is unaware of any one exchange whose membership includes every registered broker-dealer. The Exchange also believes substitutable products and services are available to market participants, including, among other things, other options exchanges that a market participant may connect to in lieu of the Exchange, indirect connectivity to the Exchange via a third-party reseller of connectivity, and/or trading of options products within markets which do not require connectivity to the Exchange, such as the Over-the-Counter (OTC) markets.

There are currently 17 exchanges offering options trading services. No single options exchange trades more than 14% of the options market by volume and only one of the 17 options exchanges has a market share over 10 percent.[15] This broad dispersion of market share demonstrates that market participants can and do exercise choice in trading venues. Further, low barriers to entry mean that new exchanges may rapidly enter the market and offer additional substitute platforms to further compete with the Exchange and the products it offers.

As such, the Exchange must set its fees, including its fees for connectivity and co-location services and products, competitively. If not, customers may move to other venues or reduce use of the Exchange's services. ''If competitive forces are operative, the self-interest of the exchanges themselves will work powerfully to constrain unreasonable or unfair behavior.'' [16] Accordingly, ''the existence of significant competition provides a substantial basis for finding that the terms of an exchange's fee proposal are equitable, fair, reasonable, and not unreasonably or unfairly discriminatory.'' [17] Disincentivizing market participants from purchasing Exchange connectivity would only serve to discourage participation on the Exchange, which ultimately does not benefit the Exchange. Moreover, if the Exchange charges excessive fees, it may stand to lose not only connectivity revenues but also other revenues, including revenues associated with the execution of orders.

In summary, the proposal represents an equitable allocation of reasonable dues, fees and other charges because Exchange fees have fallen in real terms and customers have a choice in trading venue and will exercise that choice and trade at another venue if exchange fees are not set competitively.

No Unfair Discrimination

The Exchange believes that the proposed fee changes are not unfairly discriminatory because the fees are assessed uniformly across all market participants that voluntarily subscribe to or purchase connectivity and co-location services or products, which are available to all customers.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Nothing in the proposal burdens inter-market competition (the competition among self-regulatory organizations) because approval of the proposal does not impose any burden on the ability of other exchanges to compete. The Exchange operates in a highly competitive market in which market participants can determine whether or not to connect to the Exchange based on the value received compared to the cost of doing so. Indeed, market participants have numerous alternative exchanges that they may participate on and direct their order flow, as well as off-exchange venues, where competitive products are available for trading.

Nothing in the proposal burdens intra-market competition (the competition among consumers) because

[12] *See https://www.officialdata.org/us/inflation/2017?amount=1* (Last updated February 27, 2024).

[13] As noted above, unregulated competitors providing connectivity and colocation services often have annual price increases written into their agreements with customers to account for inflation and rising costs.

[14] *See https://www.officialdata.org/us/inflation/2022?endYear=2023&amount=1.*

[15] *See* Nasdaq, Options Market Statistics (Last updated January 11, 2024), available at *https://www.nasdaqtrader.com/Trader.aspx?id=OptionsVolumeSummary.*

[16] *See* Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74,770 (December 9, 2008) (SR–NYSEArca–2006–21).

[17] *Id.*

the Exchange's connectivity and co-location services are available to any customer under the same fee schedule as any other customer, and any market participant that wishes to purchase such services can do so on a non-discriminatory basis.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[18] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–GEMX–2024–09 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–GEMX–2024–09. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–GEMX–2024–09 and should be submitted on or before June 7, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–10813 Filed 5–16–24; 8:45 am]

BILLING CODE 8011–01–P

[18] 15 U.S.C. 78s(b)(3)(A)(ii).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100122; File No. SR–CboeBYX–2024–014]

Self-Regulatory Organizations; Cboe BYX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fees Schedule To Adopt Fees for Dedicated Cores

May 13, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 6, 2024, Cboe BYX Exchange, Inc. (the ''Exchange'' or ''BYX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BYX Exchange, Inc. (the ''Exchange'' or ''BYX Equities'') proposes to amend its Fees Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/BYX/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its fee schedule to amend [sic] the fees and increase [sic] the maximum cap for Dedicated Cores.

By way of background, as of May 6, 2025, the Exchange allow Users[3] to assign a Single Binary Order Entry (''BOE'') logical order entry port[4] to a single dedicated Central Processing Unit (CPU Core) (''Dedicated Core''). Historically, CPU Cores had been shared by logical order entry ports (*i.e.,* multiple logical ports from multiple

[3] A User may be either a Member or Sponsored Participant. The term ''Member'' shall mean any registered broker or dealer that has been admitted to membership in the Exchange, limited liability company or other organization which is a registered broker or dealer pursuant to Section 15 of the Act, and which has been approved by the Exchange. A Sponsored Participant may be a Member or non-Member of the Exchange whose direct electronic access to the Exchange is authorized by a Sponsoring Member subject to certain conditions. See Exchange Rule 11.3.

[4] Users may currently connect to the Exchange using a logical port available through an application programming interface (''API''), such as the Binary Order Entry (''BOE'') protocol. A BOE logical order entry port is used for order entry.

firms may connect to a single CPU Core). Use of Dedicated Cores however, can provide reduced latency, enhanced throughput, and improved performance since a firm using a Dedicated Core is utilizing the full processing power of a CPU Core instead of sharing that power with other firms. This offering is completely voluntary and is available to all Users that wish to purchase Dedicated Cores. Users may utilize BOE logical order entry ports on shared CPU Cores, either in lieu of, or in addition to, their use of Dedicated Core(s). As such, Users are able to operate across a mix of shared and dedicated CPU Cores which the Exchange believes provides additional risk and capacity management. Further, Dedicated Cores are not required nor necessary to participate on the Exchange and as such Users may opt not to use Dedicated Cores at all.

The Exchange proposes to assess the following monthly fees for those Users that wish to use Dedicated Cores: $650 per Dedicated Core for 3–10 Dedicated Cores; $850 per Dedicated Core for 11–15 Dedicated Cores; and $1,050 per Dedicated Core for 16 or more Dedicated Cores. The proposed fees are progressive and and [sic] the Exchange proposes to include the following example in the Fees Schedule to provide clarity as to how the fees will be applied. Particularly, the Exchange will provide the following example: if a User were to purchase 11 Dedicated Cores, it will be charged a total of $6,050 per month ($0 * 2 + $650 * 8 + $850 * 1). The Exchange also proposes to make clear in the Fees Schedule that the monthly fees are assessed and applied in their entirety and are not prorated. The Exchange notes the current standard fees assessed for BOE Logical Ports, whether used with Dedicated or shared CPU cores, will remain applicable and unchanged.[5]

Since the Exchange currently has finite amount of space in its data centers in which its servers (and therefore corresponding CPU Cores) are located, the Exchange also proposes to prescribe a maximum limit on the number of Dedicated Cores that Users may purchase each month. The purpose of establishing these limits is to manage the allotment of Dedicated Cores in a fair manner and to prevent the Exchange from being required to expend large amounts of resources in order to provide an unlimited number of Dedicated Cores. Particularly, the Exchange proposes to provide that Members will be limited to a maximum number of 20 Dedicated Cores[6] and Sponsoring Members will be limited to a maximum number of 8 Dedicated Cores for each of their Sponsored Access relationships.[7] The Exchange notes that it will continue monitoring Dedicated Core interest by all Users and allotment availability with the goal of increasing these limits to meet Users' needs.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[8] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[9] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[10] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed rule change is consistent with Section 6(b)(4)[11] of the Act, which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Members and other persons using its facilities.

The Exchange believes the proposal is reasonable because the Exchange is offering any Users who wishes to utilize Dedicated Cores up to two Dedicated Cores at no additional cost. The Exchange believes the proposed fees are reasonable because Dedicated Cores provide a valuable service in that it may provide reduced latency, enhanced throughput, and improved performance compared to use of a shared CPU Core since a firm using a Dedicated Core is utilizing the full processing power of a CPU Core. The Exchange also emphasizes however, that the use of Dedicated Cores is not necessary for trading and as noted above, is entirely optional. Indeed, Users can continue to access the Exchange through shared CPU Cores at no additional cost. Depending on a firm's specific business needs, the proposal enables Users to choose to use Dedicated Cores in lieu of, or in addition to, shared CPU Cores (or as noted, not use Dedicated Cores at all). The Exchange believes the proposal to operate across a mix of shared and dedicated CPU Cores may further provide additional risk and capacity management. If a User finds little benefit in having Dedicated Cores, or determines Dedicated Cores are not cost-efficient for its needs or does not provide sufficient value to the firm, such User may continue its use of the shared CPU Cores, unchanged. Indeed, the Exchange has no plans to eliminate shared CPU Cores nor to require Users to purchase Dedicated Cores.

The Exchange also believes that the proposed Dedicated Core fees are equitable and not unfairly discriminatory because they continue to be assessed uniformly to similarly situated users in that all Users who choose to purchase Dedicated Cores will be subject to the same proposed tiered fee schedule. Further all Users are entitled to up to 2 Dedicated Cores at no additional cost. The Exchange believes the proposed ascending fee structure is also reasonable, equitable and not unfairly discriminatory as it is designed so that firms that use a higher allotment of the Exchange's finite number of Dedicated Cores pay higher rates, rather than placing that burden on market participants that have more modest needs who will have the flexibility of obtaining Dedicated Cores at lower price points in the lower tiers. As such, the

[5] The Exchange currently assesses $550 per port per month. *See* Cboe BYX Equities Fee Schedule.

[6] The prescribed maximum quantity of Dedicated Cores for Members applies regardless of whether that Member purchases the Dedicated Cores directly from the Exchange and/or through a Service Bureau. In a Service Bureau relationship, a customer allows its MPID to be used on the ports of a technology provider, or Service Bureau. One MPID may be allowed on several different Service Bureaus.

[7] The fee tier(s) applicable to Sponsoring Members are determined on a per Sponsored Access relationship basis and not on the combined total of Dedicated Cores across Sponsored Users. For example, under the proposed changes, a Sponsoring Member that has two Sponsored Access relationships is entitled to a total of 16 Dedicated Cores for those 2 Sponsored Access relationships but would be assessed fees separately based on the 8 Dedicated Cores for each Sponsored User (instead of combined total of 16 Dedicated Core). For example, a Sponsoring Member with 2 Sponsored Access relationships would be provided 2 Dedicated Cores at no additional cost for each Sponsored User under Tier 1 (total of 4 Dedicated Cores at no additional cost) and provided an additional 6 Dedicated Cores for each Sponsored User under Tier 2 (total 12 Dedicated Cores) at $650 per month.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] *Id.*

[11] 15 U.S.C. 78f(b)(4).

proposed fees do not favor certain categories of market participants in a manner that would impose a burden on competition; rather, the ascending fee structure reflects the resources consumed by the various needs of market participants—that is, the lowest Dedicated Core consuming Users pay the least, and highest Dedicated Core consuming Users pay the most. Other exchanges similarly assess higher fees to those that consume more Exchange resources.[12] It's also designed to encourage firms to manage their needs in a fair manner and to prevent the Exchange from being required to expend large amounts of resources in order to provide an additional number of Dedicated Cores.

The Exchange believes it is reasonable to limit the number of Dedicated Cores Users can purchase because the Exchange has a finite amount of space in its data centers and availability of cores. The Exchange will continually monitor market participant demand and resource availability and endeavor to adjust the limit if and when the Exchange is able to accommodate additional CPU Cores (including Dedicated Cores). The Exchange monitors its capacity and data center space and thus is in the best place to determine these limits and modify them as appropriate in response to changes to this capacity and space. The proposed limits also apply uniformly to similarly situated market participants (*i.e.,* all Members are subject to the same limit and all Sponsored Participants are subject to the same limit, respectively). The Exchange believes it's not unfairly discriminatory to provide for different limits for different types of users. For example, the Exchange believe it's not unfairly discriminatory to provide for an initial lower limit to be allocated for Sponsored Participants because unlike Members, Sponsored Participants are able to access the Exchange without paying a Membership Fee. Members also have more regulatory obligations and risk that Sponsored Participants do not. For example, while Sponsored Participants must agree to comply with the Rules of the Exchange, it is the Sponsoring Member of that Sponsored Participant that remains ultimately responsible for all orders entered on or through the Exchange by that Sponsored Participant. The industry also has a history of applying fees differently to Members as compared to Sponsored Participants.[13]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary in furtherance of the purposes of the Act because the proposed tiered fee structure will apply equally to all similarly situated Users that choose to use Dedicated Cores. As discussed above, Dedicated Cores are optional and Users may choose to utilize Dedicated Cores, or not, based on their views of the additional benefits and added value provided by utilizing a Dedicated Core. The Exchange believes the proposed fee will be assessed proportionately to the potential value or benefit received by Users with a greater number of Dedicated Cores and notes that Users may determine at any time to cease using Dedicated Cores. As discussed, Users can also continue to access the Exchange through shared CPU Cores at no additional cost. Finally, all Users will be entitled to two Dedicated Cores at no additional cost.

Next, the Exchange believes the proposed rule change does not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As previously discussed, the Exchange operates in a highly competitive market, including competition for exchange memberships. Market Participants have numerous alternative venues that they may participate on, including 15 other equities exchanges, as well as off-exchange venues, where competitive products are available for trading. Indeed, participants can readily choose to submit their order flow to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [14] The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .''.[15] Accordingly, the Exchange does not believe its proposed change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [16] and paragraph (f) of Rule 19b–4 [17] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act.

[12] *See also* Cboe U.S. Options Fees Schedule, BZX Options, Options Logical Port Fees, Ports with Bulk Quoting Capabilities.

[13] *See e.g.,* Securities Exchange Act Release No. 68342 (December 3, 2012) 77 FR 73096 (December 7, 2012) (SR–CBOE–2012–114).and Securities Exchange Act Release No. 66082 (January 3, 2012) 77 FR 1101 (January 9, 2012) (SR–C2–2011–041).

[14] See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[15] *NetCoalition* v. *SEC,* 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f).

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeBYX–2024–014 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–CboeBYX–2024–014. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeBYX–2024–014 and should be submitted on or before June 7, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–10817 Filed 5–16–24; 8:45 am]

BILLING CODE 8011–01–P

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100123; File No. SR–ISE–2024–18]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend ISE Options 7

May 13, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 7, 2024, Nasdaq ISE, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend ISE's Pricing Schedule at Options 7.[3]

While the changes proposed herein are effective upon filing, the Exchange has designated the pricing changes become operative on August 1, 2024, with the exception of the Exposed Order definition and Dedicated Gateway amendments which would be effective on September 1, 2024.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/ise/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange withdrew SR–ISE–2024–15 on May 7, 2024 and submitted this filing.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

ISE proposes to amend its Pricing Schedule at Options 7. Specifically, ISE proposes to: (1) add the defined term ''Exposed Order'' within Options 7, Section 1(c); (2) amend Options 7, Section 7.C to offer certain free ports in connection with an upcoming technology migration; [4] and (3) amend Options 7, Section 8.C to discontinue offering Dedicated Gateway access services. Each change is described below.

Options 7, Section 1

The Exchange proposes to define an Exposed Order for purposes of pricing within Options 7. The Exchange introduced the concept of an ''exposure'' in a rule change amending ISE's routing rules.[5] In that rule change, the Exchange noted that for purposes of ISE's Options 5, Section 4 routing rule, ''exposure'' or ''exposing'' an order means a notification sent to Members with the price, size, and side of interest that is available for execution.[6] The order exposure will apply to both routed orders and non-routed or ''DNR Orders.'' The order exposure process permits the Exchange to apply a Route Timer [7] prior to the initial and subsequent routing of an order and allows routing of the order after exposure occurs (during open trading) every time an order becomes marketable against the ABBO.[8]

At this time, the Exchange proposes to amend Options 7, Section 1(c) to provide,

[4] *See* Options Trader Alert #2024–5. The ISE migration will commence on September 9, 2024.

[5] *See* Securities Exchange Act Release No. 94897 (May 12, 2022), 87 FR 30294 (May 18, 2022) (SR–ISE–2022–11) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Routing Functionality in Connection With a Technology Migration). *See also* Securities Exchange Act Release No. 97126 (March 13, 2023), 88 FR 16485 (March 17, 2023) (SR–ISE–2023–04) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Delay the Implementation of Certain Trading Functionality).

[6] *See* ISE Options 5, Section 4(a) which is effective but not yet operative. *See supra* note 4.

[7] For purposes of Options 5, Section 4, a Route Timer shall not exceed one second and shall begin at the time orders are accepted into the System, and the System will consider whether an order can be routed at the conclusion of each Route Timer.

[8] *See supra* note 4.

An ''Exposed Order'' is an order that is broadcast via an order exposure alert as described within Options 5, Section 4 (Order Routing). Unless otherwise noted in Options 7, Section 3 pricing, Exposed Orders will be assessed the applicable ''Taker'' Fee and any order or quote that executes against an Exposed Order during a Route Timer will be paid/assessed the applicable ''Maker'' Rebate/Fee.

As proposed, the defined term would apply a Taker Fee, where applicable, to an executed Exposed Order. If an order or quote allocates against the Exposed Order during the Route Timer described within Options 5, Section 4, the Exchange would pay/assess the applicable Maker Rebate or Maker Fee. The Exchange believes that its proposal should provide increased opportunities for participation in executions on the Exchange, facilitating the ability of the Exchange to bring together participants and encourage more robust competition for orders.

Options 7, Section 6

In connection with a technology migration,[9] Members may request new FIX Ports,[10] SQF Ports,[11] SQF Purge Ports,[12] OTTO Ports,[13] CTI Ports,[14] and FIX DROP Ports,[15] at no additional cost, from August 1, 2024 through October 31, 2024 (''Transition Period'') which are duplicative of the type and quantity of their legacy ports. These second set of new ports would allow Members time to test ports to the new environment as well as provide continuous connection to the Exchange's match engine during the Transition Period.[16] During the Transition Period, Members will be required to utilize their new ports on the new ISE platform for symbols that have migrated to the new platform, while continuing to leverage legacy ports for symbols that have not yet migrated to the new platform.[17] For example, an ISE Member with 3 legacy SQF Ports, 1 legacy SQF Purge Port, 1 legacy FIX DROP Port, 1 legacy OTTO Port, and 1 legacy CTI Port on August 1, 2024 could request the equivalent quantity and type of new ports (3 SQF Ports, 1 SQF Purge Port, 1 FIX DROP Port, 1 OTTO Port, and 1 CTI Port) for the new ISE environment during the Transition Period at no additional cost. During the Transition Period, the ISE Member would be assessed only for legacy ports and would not be assessed for the new ports, which are duplicative of the legacy ports.

A Member may acquire additional legacy ports during the Transition Period and would be assessed the charges indicated in the current Pricing Schedule at Options 7, Section 7.C, respectively, for those additional legacy ports.

The technology migration does not require a Member to acquire any additional legacy ports or any specific number of new ports, rather the technology migration requires a new port to connect to the new ISE environment. As is the case today, a Member may decide the number of ports they desire to subscribe to on the new technology platform.[18]

Of note, only ISE Members may utilize ports on ISE and only one port is necessary to submit orders to ISE. Similarly, a Market Maker quoting on ISE only requires 1 SQF Port.[19] A Member may also obtain any number of order and execution ports, such as a SQF Purge Ports, FIX DROP Ports and CTI Ports and any number of market data ports.[20] Members are able to elect the quantity and type of ports they purchase based on that Member's business model.[21]

This proposal is not intended to impose any additional fees on any ISE Member. Rather, this proposal is intended to permit an ISE Member to utilize the new environment with the same type and quantity of legacy ports, at no additional cost, during the Transition Period.

Starting November 1, 2024, the port fees in Options 7, Section 7.C would apply to any substituted ports that a Member continues to subscribe to after the Transition Period. ISE will sunset legacy FIX Ports, SQF Ports, SQF Purge Ports, OTTO Ports, CTI Ports and FIX DROP Ports on December 20, 2024.

Options 7, Section 8

Today, ISE offers Market Makers the ability to access the Exchange through a

[9] ISE is migrating its technology to an enhanced Nasdaq, Inc. functionality which results in higher performance, scalability, and more robust architecture.

[10] ''Financial Information eXchange'' or ''FIX'' is an interface that allows Members and their Sponsored Customers to connect, send, and receive messages related to orders and auction orders to the Exchange. Features include the following: (1) execution messages; (2) order messages; (3) risk protection triggers and cancel notifications; and (4) post trade allocation messages. *See* Supplementary Material .03(a) to Options 3, Section 7.

[11] ''Specialized Quote Feed'' or ''SQF'' is an interface that allows Market Makers to connect, send, and receive messages related to quotes, Immediate-or-Cancel Orders, and auction responses to the Exchange. Features include the following: (1) options symbol directory messages (*e.g.,* underlying instruments); (2) System event messages (*e.g.,* start of trading hours messages and start of opening); (3) trading action messages (*e.g.,* halts and resumes); (4) execution messages; (5) quote messages; (6) Immediate-or-Cancel Order messages; (7) risk protection triggers and purge notifications; (8) opening imbalance messages; (9) auction notifications; and (10) auction responses. The SQF Purge Interface only receives and notifies of purge requests from the Market Maker. Market Makers may only enter interest into SQF in their assigned options series. *See* Supplementary Material .03(c) to Options 3, Section 7.

[12] SQF Purge is a specific port for the SQF interface that only receives and notifies of purge requests from the Market Maker. Dedicated SQF Purge Ports enable Market Makers to seamlessly manage their ability to remove their quotes in a swift manner.

[13] ''Ouch to Trade Options'' or ''OTTO'' is an interface that allows Members and their Sponsored Customers to connect, send, and receive messages related to orders, auction orders, and auction responses to the Exchange. Features include the following: (1) options symbol directory messages (*e.g.,* underlying instruments); (2) System event messages (*e.g.,* start of trading hours messages and start of opening); (3) trading action messages (*e.g.,* halts and resumes); (4) execution messages; (5) order messages; (6) risk protection triggers and cancel notifications; (7) auction notifications; (8) auction responses; and (9) post trade allocation messages. *See* Supplementary Material .03(b) to Options 3, Section 7.

[14] Clearing Trade Interface (''CTI'') is a real-time cleared trade update message that is sent to a Member after an execution has occurred and contains trade details specific to that Member. The information includes, among other things, the following: (i) The Clearing Member Trade Agreement (''CMTA'') or The Options Clearing Corporation (''OCC'') number; (ii) badge or mnemonic; (iii) account number; (iv) information which identifies the transaction type (*e.g.* auction type) for billing purposes; and (v) market participant capacity. *See* Option 3, Section 23(b)(1).

[15] FIX DROP is a real-time order and execution update message that is sent to a Member after an order been received/modified or an execution has occurred and contains trade details specific to that Member. The information includes, among other things, the following: (i) executions; (ii) cancellations; (iii) modifications to an existing order; and (iv) busts or post-trade corrections. *See* Options 3, Section 23(b)(3).

[16] Members would contact Market Operations to acquire new duplicative ports.

[17] *See* Options Trader Alert #2024–5. The ISE migration will commence on September 9, 2024 and end on September 23, 2024.

[18] The technology migration is 1:1 and therefore would not require a Member to acquire an additional quantity of new ports, nor would it reduce the total number of ports needed to connect to the match engine.

[19] SQF Ports are utilized solely by Market Makers who are the only Members permitted to quote on ISE.

[20] ISE does not assess fees for the market data ports within Options 7, Section 7.C(iii). Members may acquire any number of market data ports at no cost.

[21] For example, a Member may desire to utilize multiple FIX or OTTO Ports for accounting purposes, to measure performance, for regulatory reasons or other determinations that are specific to that Member.

Dedicated Gateway. Only Market Makers that utilize SQF ports have the option of utilizing this dedicated offering. Today, all other ports, namely FIX, OTTO and Precise, are subject to shared access through a Shared Gateway, at no cost, while an SQF port has the options of shared access, at no cost, or dedicated access. Today, ISE charges a fee of $2,250 per SQF gateway, per month, for dedicated access.

At this time, ISE proposes to discontinue Dedicated Gateway access for SQF Ports as of September 1, 2024. Similar to FIX, OTTO and Precise, SQF Ports will have shared access through a Shared Gateway at no cost.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[22] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[23] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange's proposed changes to its Pricing Schedule are reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for options securities transaction services that constrain its pricing determinations in that market. The fact that this market is competitive has long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .'' [24]

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [25]

Numerous indicia demonstrate the competitive nature of this market. For example, clear substitutes to the Exchange exist in the market for options security transaction services. The Exchange is only one of seventeen options exchanges to which market participants may direct their order flow. Within this environment, market participants can freely and often do shift their order flow among the Exchange and competing venues in response to changes in their respective pricing schedules. As such, the proposal represents a reasonable attempt by the Exchange to increase its liquidity and market share relative to its competitors.

Options 7, Section 1

The Exchange's proposal to define an Exposed Order for purposes of pricing within Options 7, Section 1(c) is reasonable because it will provide Members information as to the manner in which pricing will be applied to both the Exposed Order as well as an order or quote that allocates against the Exposed Order.[26] As proposed, the applicable Taker Fee would apply to an executed Exposed Order and the applicable Maker Rebate or Maker Fee would apply to an order or quote that allocated against the Exposed Order during the Route Timer. The Exchange believes the proposed pricing should provide increased opportunities for participation in executions on the Exchange, facilitating the ability of the Exchange to bring together participants and encourage more robust competition for orders. Order exposure has the potential to result in more efficient executions for participants as responses to exposed orders could result in faster executions. Order exposure assures that such exposed orders will only receive executions at a price at least as good as the price disseminated by the best away market at the time the order was received. Further, the Exchange believes that it is reasonable, equitable and not unfairly discriminatory to apply the Taker Fee to Exposed Orders and the Maker Rebate/Fee to any order or quote that executes against an Exposed Order during a Route Timer because the Exposed Order that would route to an away market if not otherwise executed on ISE would be taking liquidity from the Exchange's order book while a quote or order that executes against the Exposed Order during the Route Timer would be considered making liquidity in response to the notification sent to Members indicating the order is available for execution. Nasdaq MRX, LLC (''MRX'') and Nasdaq GEMX, LLC (''GEMX'') similarly assess a Taker Fee to an exposed order and pay/assess a Maker Rebate/Fee to any order or quote that executes against the exposed order during the Route Timer.[27]

The Exchange's proposal to define an Exposed Order for purposes of pricing within Options 7, Section 1(c) is equitable and not unfairly discriminatory as the proposed pricing for Exposed Orders would be uniformly applied to all orders subject to the Exchange's Route Timer, as described in Options 5, Section 4.

Options 7, Section 6

The proposed amendments to Options 7, Section 7.C to permit Members to acquire a second set of FIX Ports, SQF Ports, SQF Purge Ports, OTTO Ports, CTI Ports and FIX DROP Ports, at no cost, as part of the technology migration are reasonable because they will permit ISE Members to migrate to the new platform without a pricing impact. Specifically, the proposal is intended to permit ISE Members to migrate their legacy FIX Ports, SQF Ports, SQF Purge Ports, OTTO Ports, CTI Ports and FIX DROP Ports to new ports at no additional cost during the Transition Period. This proposal will allow Members to test their ports and maintain continuous connection to the Exchange's match engine during the Transition Period.

The proposed amendments to Options 7, Section 7.C to permit Members to acquire a second set of FIX Ports, SQF Ports, SQF Purge Ports, OTTO Ports, CTI Ports and FIX DROP Ports, at no cost, as part of the technology migration are equitable and not unfairly discriminatory because no Member would have a pricing impact as a result of this proposal, provided the Member did not obtain additional new ports to connect to the ISE environment beyond the quantity and type the Member had on August 1, 2024 or additional legacy ports. No Member would be assessed a fee for the new second set of ports, provided they acquired a new second set of ports commiserate with the type and quantity of ports they subscribed to

[22] *See* 15 U.S.C. 78f(b).

[23] *See* 15 U.S.C. 78f(b)(4) and (5).

[24] *NetCoalition* v. *SEC,* 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[25] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[26] *See* Option 5, Section 4.

[27] *See* MRX and GEMX Options 7, Section 1(c).

as of August 1, 2024. A Member obtaining additional legacy ports, beyond the current type and quantity of ports they have as of August 1, 2024, would be assessed the fees noted in Options 7, Section 7.C as applicable. ISE will sunset legacy FIX Ports, SQF Ports, SQF Purge Ports, OTTO Ports, CTI Ports and FIX DROP Ports on December 20, 2024 for all Members. Starting November 1, 2024, the port fees in Options 7, Section 7.C would apply to any substituted ports that a Member continues to subscribe to after the Transition Period.

The technology migration does not require a Member to acquire any additional quantity of new ports, nor would it reduce the total number of ports needed to connect to the match engine. Rather the technology migration requires a new port to replace any legacy port provided the Member desired to maintain the same number of ports on the new ISE technology platform. Of note, only ISE Members may utilize ports on ISE and only one port is necessary to submit orders to ISE. Similarly, a Market Maker quoting on ISE only requires 1 SQF Port.[28] A Member may also obtain any number of order and execution ports, such as a SQF Purge Ports, FIX DROP Ports and CTI Ports and any number of market data ports.[29] Members are able to elect the quantity and type of ports they purchase based on that Member's business model.[30]

Options 7, Section 8

The Exchange's proposal to discontinue Dedicated Access for SQF Ports as of September 1, 2024 is reasonable as all ports (FIX, OTTO, Precise, SQF Ports) would utilize a shared gateway to access the Exchange. There is no cost to utilize the Shared Gateway on ISE. The Exchange notes that GEMX and MRX do not offer Shared Gateways, rather they utilize shared access to all Members for all ports.

The Exchange's proposal to discontinue Dedicated Access for SQF Ports as of September 1, 2024 is equitable and not unfairly discriminatory as all access to the Exchange for all Members, for all ports will be at no cost through shared access.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Intermarket Competition

The Exchange believes its proposal remains competitive with other options markets, and will offer market participants with another choice of venue to transact options. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

Intramarket Competition

Options 7, Section 1

The Exchange's proposal to define an Exposed Order for purposes of pricing within Options 7, Section 1(c) does not impose an undue burden on competition because the proposed pricing for Exposed Orders would be uniformly applied to all orders subject to the Exchange's Route Timer, as described in Options 4, Section 5.

Options 7, Section 6

The proposed amendments to Options 7, Section 7.C to permit Members to acquire a second set of FIX Ports, SQF Ports, SQF Purge Ports, OTTO Ports, CTI Ports and FIX DROP Ports, at no cost, as part of the technology migration do not impose an undue burden on competition because no Member would have a pricing impact as a result of this proposal, provided the Member did not obtain additional new ports to connect to the ISE environment beyond the quantity and type the Member had on August 1, 2024 or additional legacy ports. No Member would be assessed a fee for the new second set of ports, provided they acquired a new second set of ports commiserate with the type and quantity of ports they subscribed to as of August 1, 2024. A Member obtaining additional legacy ports, beyond the current type and quantity of ports they have as of August 1, 2024, would be assessed the fees noted in Options 7, Section 7.C as applicable. ISE will sunset legacy FIX Ports, SQF Ports, SQF Purge Ports, OTTO Ports, CTI Ports and FIX DROP Ports on December 20, 2024 for all Members. Starting on November 1, 2024 the port fees in Options 7, Section 7.C would apply to any substituted ports that a Member continues to subscribe to after the Transition Period.

Options 7, Section 8

The Exchange's proposal to discontinue Dedicated Access for SQF Ports as of September 1, 2024 does not impose an undue burden on competition as all access to the Exchange for all Members, for all ports will be at no cost through shared access.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[31] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–ISE–2024–18 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange

[28] SQF Ports are utilized solely by Market Makers who are the only Members permitted to quote on ISE.

[29] ISE does not assess fees for the market data ports within Options 7, Section 7.C(iii). Members may acquire any number of market data ports at no cost.

[30] For example, a Member may desire to utilize multiple FIX or OTTO Ports for accounting purposes, to measure performance, for regulatory reasons or other determinations that are specific to that Member.

[31] 15 U.S.C. 78s(b)(3)(A)(ii).

Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–ISE–2024–18. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–ISE–2024–18 and should be submitted on or before June 7, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[32]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–10818 Filed 5–16–24; 8:45 am]

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[32] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100121; File No. SR–MRX–2024–10]

Self-Regulatory Organizations; Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Fees for Connectivity and Co-Location Services

May 13, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 29, 2024, Nasdaq MRX, LLC (''MRX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's fees for connectivity and co-location services, as described further below.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/mrx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's fees relating to connectivity and co-location services.[3] Specifically, the Exchange proposes to raise its fees for connectivity and co-location services in General 8 as well as certain fees related to its Testing Facilities in Options 7, Section 7 by 5.5%, with certain exceptions.

General 8, Section 1 includes the Exchange's fees that relate to connectivity, including fees for cabinets, external telco/inter-cabinet connectivity fees, fees for connectivity to the Exchange, fees for connectivity to third party services, fees for market data connectivity, fees for cabinet power install, and fees for additional charges and services. General 8, Section 2 includes the Exchange's fees for direct connectivity services, including fees for direct circuit connection to the Exchange, fees for direct circuit connection to third party services, and fees for point of presence connectivity. With the exception of the Exchange's GPS Antenna fees and the Cabinet Proximity Option Fee for cabinets with power density >10kW,[4] the Exchange proposes to increase its fees throughout General 8 by 5.5%.

In addition to increasing fees in General 8, the Exchange also proposes to increase certain fees in Options 7, Section 7, which relate to the Testing Facility. Options 7, Section 7 provides that subscribers to the Testing Facility located in Carteret, New Jersey shall pay a fee of $1,000 per hand-off, per month for connection to the Testing Facility. The hand-off fee includes either a 1Gb or 10Gb switch port and a cross connect to the Testing Facility. In addition, Options 7, Section 7 provides that subscribers shall also pay a one-time installation fee of $1,000 per hand-off. The Exchange proposes to increase these aforementioned fees by 5.5% to require that subscribers to the Testing Facility shall pay a fee of $1,055 per hand-off, per month for connection to the Testing Facility and a one-time installation fee of $1,055 per hand-off.

The proposed increases in fees would enable the Exchange to maintain and improve its market technology and services. The Exchange has not increased any of the fees included in the proposal since 2017.[5] However, since 2017, there has been notable inflation. Between 2017 and 2024, the dollar had an average inflation rate of 3.34% per year, producing a cumulative price

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange initially filed the proposed pricing change on March 1, 2024 (SR–MRX–2024–04). The instant filing replaces SR–MRX–2024–04, which was withdrawn on April 29, 2024.

[4] The Exchange proposes to exclude the GPS Antenna fees from the proposed fee increase because, unlike the other fees in General 8, the Exchange recently increased its GPS Antenna fees. *See* Securities Exchange Act Release No. 34–99130 (December 11, 2023), 88 FR 87009 (December 15, 2023) (SR–MRX–2023–24). The Exchange also proposes to exclude the Cabinet Proximity Option Fee for cabinets with power density >10kW from the proposed fee increase because the Exchange recently established such fee. *See* Securities Exchange Act Release No. 34–99798 (March 20, 2024), 89 FR 21126 (March 26, 2024) (SR–MRX–2024–09).

[5] *See* Securities Exchange Act Release No. 34–81907 (October 19, 2017), 82 FR 49447 (October 25, 2017) (SRMRX–2017–21).

increase of 25.82%.[6] Notwithstanding inflation, the Exchange historically has not increased its fees every year.[7] The proposed fees represent a 5.5% increase from the current fees, which is far below inflation since 2017, which exceeded 25%. In addition to being far below the cumulative inflation rate since 2017, the Exchange also believes that the proposed 5.5% increase is reasonable because it is comparable to recent inflation rates for one-year periods. For example, in 2023, the inflation rate was 4.12% and in 2022, the inflation rate was 8%.[8] The Exchange is sensitive to the sticker shock that would occur if the Exchange raised its fees by more than 25% and therefore proposes a more modest increase, similar to that of inflation in recent one-year periods.

The Exchange believes that it is reasonable to increase its fees to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2017. The Exchange notes that this inflationary effect is a general phenomenon that is independent of any change in the Exchange's costs in providing its goods and services. The Exchange believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects. The Exchange notes that other exchanges have filed for comparable or higher increases in certain connectivity-related fees, based in part on similar rationale.[9]

In addition, the Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding the Exchange's existing co-location facility to offer customers additional space and power. These investments, and the value they provide to customers, far exceed the amount of the proposed price increases. It is reasonable and consistent with the Act for the Commission to allow the Exchange to recoup these investments by charging fees, lest the Commission will disincentivize the Exchange to make similar investments in the future—a result that would be detrimental to the Exchange's competitiveness as well as the interests of market participants and investors.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[11] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

This belief is based on a couple factors. First, the current fees do not properly reflect the value of the services and products, as fees for the services and products in question have been static in nominal terms, and therefore falling in real terms due to inflation. Second, exchange fees are constrained by the fact that market participants can choose among 17 different venues for options trading, and therefore no single venue can charge excessive fees for its products without losing customers and market share.

Real Exchange Fees Have Fallen

As explained above, the Exchange has not increased any of the fees included in the proposal since 2017. This means that such fees have fallen in real terms due to inflation, which has been notable. Between 2017 and 2024, the dollar had an average inflation rate of 3.34% per year, producing a cumulative price increase of 25.82%.[12] Notwithstanding inflation, the Exchange historically has not increased its fees every year.[13] As noted above, the Exchange has not increased the fees in this proposal for over 6 years. Accordingly, the Exchange believes that the proposed fees are reasonable as they represent a 5.5% increase from the current fees, which is far below inflation since 2017, which exceeded 25%. In addition to being far below the inflation rate since 2017, the Exchange also believes that the proposed 5.5% increase is reasonable because it is comparable to recent inflation rates for one-year periods. For example, in 2023, the inflation rate was 4.12% and in 2022, the inflation rate was 8%.[14] The Exchange is sensitive to the sticker shock that would occur if the Exchange raised its fees by more than 25% and therefore proposes a more modest increase, similar to that of inflation in recent one-year periods.

The Exchange believes that it is reasonable to increase its fees to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2017. The Exchange notes that this inflationary effect is a general phenomenon that is independent of any change in the Exchange's costs in providing its goods and services. The Exchange believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects.

In addition, the Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding the Exchange's existing co-location facility to offer customers additional space and power. Again, these investments, and the value they provide to customers, far exceed the amount of the proposed price increases. It is reasonable and consistent with the Act for the Commission to allow the Exchange to recoup these investments by charging fees, lest the Commission will disincentivize the Exchange to make similar investments in the future—a result that would be detrimental to the Exchange's competitiveness as well as the interests of market participants and investors.

Customers Have a Choice in Trading Venue

Customers face many choices in where to trade options. Market participants will continue to choose trading venues and the method of connectivity based on their specific needs. No broker-dealer is required to become a Member of the Exchange. There is no regulatory requirement that any market participant connect to any one exchange, nor that any market participant connect at a particular connection speed or act in a particular capacity on the Exchange, or trade any particular product offered on an exchange. Moreover, membership is not a requirement to participate on the

[6] *See https://www.officialdata.org/us/inflation/2017?amount=1* (Last updated February 27, 2024).

[7] Unregulated competitors providing connectivity and colocation services often have annual price increases written into their agreements with customers to account for inflation and rising costs.

[8] *See https://www.officialdata.org/us/inflation/2022?endYear=2023&amount=1.*

[9] *See, e.g.,* Securities Exchange Act Release No. 34–100004 (April 22, 2024), 89 FR 32465 (April 26, 2024) (SR–CboeBYX–2024–012).

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4) and (5).

[12] *See https://www.officialdata.org/us/inflation/2017?amount=1* (Last updated February 27, 2024).

[13] As noted above, unregulated competitors providing connectivity and colocation services often have annual price increases written into their agreements with customers to account for inflation and rising costs.

[14] *See https://www.officialdata.org/us/inflation/2022?endYear=2023&amount=1.*

Exchange. Indeed, the Exchange is unaware of any one exchange whose membership includes every registered broker-dealer. The Exchange also believes substitutable products and services are available to market participants, including, among other things, other options exchanges that a market participant may connect to in lieu of the Exchange, indirect connectivity to the Exchange via a third-party reseller of connectivity, and/or trading of options products within markets which do not require connectivity to the Exchange, such as the Over-the-Counter (OTC) markets.

There are currently 17 exchanges offering options trading services. No single options exchange trades more than 14% of the options market by volume and only one of the 17 options exchanges has a market share over 10 percent.[15] This broad dispersion of market share demonstrates that market participants can and do exercise choice in trading venues. Further, low barriers to entry mean that new exchanges may rapidly enter the market and offer additional substitute platforms to further compete with the Exchange and the products it offers.

As such, the Exchange must set its fees, including its fees for connectivity and co-location services and products, competitively. If not, customers may move to other venues or reduce use of the Exchange's services. ''If competitive forces are operative, the self-interest of the exchanges themselves will work powerfully to constrain unreasonable or unfair behavior.'' [16] Accordingly, ''the existence of significant competition provides a substantial basis for finding that the terms of an exchange's fee proposal are equitable, fair, reasonable, and not unreasonably or unfairly discriminatory.'' [17] Disincentivizing market participants from purchasing Exchange connectivity would only serve to discourage participation on the Exchange, which ultimately does not benefit the Exchange. Moreover, if the Exchange charges excessive fees, it may stand to lose not only connectivity revenues but also other revenues, including revenues associated with the execution of orders.

In summary, the proposal represents an equitable allocation of reasonable dues, fees and other charges because Exchange fees have fallen in real terms and customers have a choice in trading venue and will exercise that choice and trade at another venue if exchange fees are not set competitively.

No Unfair Discrimination

The Exchange believes that the proposed fee changes are not unfairly discriminatory because the fees are assessed uniformly across all market participants that voluntarily subscribe to or purchase connectivity and co-location services or products, which are available to all customers.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Nothing in the proposal burdens inter-market competition (the competition among self-regulatory organizations) because approval of the proposal does not impose any burden on the ability of other exchanges to compete. The Exchange operates in a highly competitive market in which market participants can determine whether or not to connect to the Exchange based on the value received compared to the cost of doing so. Indeed, market participants have numerous alternative exchanges that they may participate on and direct their order flow, as well as off-exchange venues, where competitive products are available for trading.

Nothing in the proposal burdens intra-market competition (the competition among consumers) because the Exchange's connectivity and co-location services are available to any customer under the same fee schedule as any other customer, and any market participant that wishes to purchase such services can do so on a non-discriminatory basis.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[18] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–MRX–2024–10 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–MRX–2024–10. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or

[15] *See* Nasdaq, Options Market Statistics (Last updated January 11, 2024), available at *https://www.nasdaqtrader.com/Trader.aspx?id=OptionsVolumeSummary.*

[16] *See* Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770 (December 9, 2008) (SR–NYSEArca–2006–21).

[17] *Id.*

[18] 15 U.S.C. 78s(b)(3)(A)(ii).

subject to copyright protection. All submissions should refer to file number SR–MRX–2024–10 and should be submitted on or before June 7, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–10816 Filed 5–16–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100114; File No. SR–CboeEDGX–2024–009]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Order Instituting Proceedings To Determine Whether To Approve or Disapprove Proposed Rule Change To Amend the Definition of Retail Order, and Codify Interpretations and Policies Regarding Permissible Uses of Algorithms by RMOs

May 13, 2024.

I. Introduction

On January 25, 2024, Cboe EDGX Exchange, Inc (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend the definition of Retail Order,[3] and codify interpretations and policies regarding permissible uses of algorithms by Retail Member Organizations.[4] The proposed rule change was published for comment in the **Federal Register** on February 13, 2024.[5] On March 20, 2024, pursuant to Section 19(b)(2) of the Act,[6] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[7] The Commission did not receive any comments. The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act[8] to determine whether to approve or disapprove the proposed rule change.

II. Description of the Proposed Rule Change[9]

Currently, the Exchange offers order book priority benefits to Retail Orders that are entered on behalf of retail investors that enter a limited number of equity orders each trading day.[10] RMOs that enter Retail Priority Orders are required to have reasonable policies and procedures in place to ensure that such orders are appropriately represented on the Exchange.[11] Pursuant to Exchange Rule 11.21(a)(2), a Retail Order is an agency order or riskless principal that meets the criteria of FINRA Rule 5320.03 that originates from a natural person and is submitted to the Exchange by a Retail Member Organization, provided that no change is made to the terms of the order with respect to price or side of market and the order does not originate from a trading algorithm or any other computerized methodology. The Exchange also states that it offers retail-only pricing incentives and offers RMO discounts on port fees and market data, and that retail tiers give growing retail firms additional rebates.[12]

The Exchange states it has received member feedback that its rule is unclear as to whether the use of algorithms or other computerized methodologies is permitted when submitting individual investors' orders to the Exchange,[13] and proposes to amend its definition of Retail Order to provide that the use of an algorithm to submit orders to the Exchange on behalf of a retail investor does not automatically preclude an RMO from designating such orders as ''Retail Orders.''[14] The Exchange proposes that use of an algorithm to submit a Retail Order would be permissible, provided that the order, or investment criteria for the order, originates from a natural person, such as the investor themselves, or a natural person on behalf of a retail investor (such as a financial advisor or trader).[15] The Exchange states that the proposed definition could encourage additional members to become RMOs and route their Retail Orders to the Exchange, and that if more members chose to become RMOs, there will be additional opportunities to interact with retail order flow, which is likely to incentivize more retail liquidity provision, as it is generally considered preferable to trade with retail orders than with orders of professional investors that are typically more informed regarding short-term price movements.[16]

In connection with the proposed amendments to its definition of Retail Order, the Exchange is proposing to adopt several Interpretations and Policies to describe: (1) the meaning of the term ''retail investor'' as used in the definition, (2) the meaning of the term ''natural person'' as used in the definition, (3) permissible uses of algorithms when entering Retail Orders onto the Exchange, and (4) when an RMO may amend a Retail Order's price or side. First, the Exchange is proposing Interpretation and Policy .01 to describe that the term ''retail investor'' is intended to refer to a non-professional, individual investor that invests money in their own account held at a brokerage firm or online brokerage firm, or an account held in corporate form for the benefit of an individual or group of related family members, and whose investment goals are mainly saving for

[19] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''Retail Order'' is defined in Exchange Rule 11.21(a)(2). *See infra* section II.

[4] The term ''Retail Member Organization'' (or ''RMO'') is defined in Exchange Rule 11.21(a)(1) to mean a member of the Exchange (or a division thereof) that has been approved by the Exchange under Exchange Rule 11.21 to submit Retail Orders.

[5] *See* Securities Exchange Act Release No. 99490 (February 7, 2024), 89 FR 10129 (''Notice'').

[6] 15 U.S.C. 78s(b)(2).

[7] *See* Securities Exchange Act Release No. 99811, 89 FR 21077 (March 26, 2024) (designating May 13, 2024, as the date by which the Commission shall either approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change).

[8] 15 U.S.C. 78s(b)(2)(B).

[9] For a full description of the proposed rule change, refer to the Notice, *supra* note 5. The text of the Exchange's proposed Rule 11.21(a)(2) and Interpretations and Policies .01–.04 is available on the Commission's website at *https://www.sec.gov/files/rules/sro/cboeedgx/2024/34-99490-ex5.pdf.*

[10] *See* Exchange Rule 11.9 and Interpretation and Policy .01 to Exchange Rule 11.9. *See also* Securities Exchange Act Release No. 87200 (October 2, 2019), 84 FR 53788, 53789 (October 8, 2019) (order granting approval of the Exchange's proposed rule change to introduce retail priority) (''Retail Priority Approval Order''). Interpretation and Policy .01 to Exchange Rule 11.9 defines a Retail Priority Order as a Retail Order (as defined in Exchange Rule 11.21(a)(2)) that is entered on behalf of a person that does not place more than 390 equity orders per day on average for its own beneficial account(s). *See* Interpretation and Policy .01 to Exchange Rule 11.9; Notice, *supra* note 5, at 10134. The Exchange refers to its retail priority offering as its ''Retail Priority program.'' *See, e.g.,* Notice, *supra* note 5, at 10130.

[11] *See* Interpretation and Policy .02 to Exchange Rule 11.9. *See also* Retail Priority Approval Order, *supra* note 10, at 53789–90.

[12] *See* Notice, *supra* note 5, at 10130.

[13] *Id,*

[14] *Id.*

[15] *Id.* Pursuant to proposed Exchange Rule 11.21(a)(2), a Retail Order would be defined as an agency or riskless principal order that meets the criteria of FINRA Rule 5320.03, and would require a Retail Order to originate from a natural person, such as the retail investors themselves, or by a natural person on behalf of a retail investor, and be submitted to the Exchange by a Retail Member Organization. In submitting a Retail Order to the Exchange, a Retail Member Organization may utilize an algorithm or other computerized methodology, provided the terms or investment criteria of the order originate from a retail investor her/himself, or a natural person on behalf of a retail investor, and the algorithm or other computerized methodology does not change the terms or investment criteria of the Retail Order with respect to price or side.

[16] *Id.* at 10130–31.

retirement or education, generating income, or growing wealth over the long term.[17]

Second, the Exchange is proposing to adopt Interpretation and Policy .02 to describe the meaning of the term ''natural person'' as referenced in the Exchange's proposed definition of Retail Order. The Exchange states that it intends for the term ''natural person'' to refer to a human who enters an order or investment criteria for an order, and that this individual may be the retail investor him/herself, or a natural person entering the order on behalf of a retail investor, such as a financial advisor or trader.[18] According to the Exchange, this will help to ensure that only bona fide retail orders are submitted to the Exchange as Retail Orders by making clear that orders generated automatically by an algorithm, without human intervention, shall not be considered Retail Orders.[19]

Third, the Exchange states that it seeks to ensure that only bona fide retail flow is designated as a Retail Order and does not intend for professional investors and professional trading firms to avail themselves of the benefits provided to RMOs by the Exchange, and is therefore proposing to adopt Interpretation and Policy .03 to describe how an RMO can permissibly utilize an algorithm when entering Retail Orders onto the Exchange. The Exchange states that an RMO could utilize an algorithm to enter individual investors' orders onto the Exchange, and permissibly designate such orders as Retail Orders, provided the order or investment criteria used to generate an order originates from a natural person, such as the retail investor him/herself, or a natural person on behalf of a retail investor, and is submitted to the Exchange for execution by an RMO.[20] The Exchange states that, conversely, orders automatically generated and submitted to the Exchange by an algorithm based on factors such as market conditions and price movements, which do not originate from a manual entry of order terms or investment criteria by a natural person, shall not be considered Retail Orders.[21]

Fourth, the Exchange is proposing to adopt Interpretation and Policy .04 to provide that post-order entry an RMO may algorithmically amend the Retail Order's price or size provided such amendments are made for the purposes of seeking better execution, enhancing execution quality, or minimizing market impact, despite the provision in the Exchange's proposed definition of Retail Order that would otherwise prohibit the changing of the price or side of a Retail Order.[22] The Exchange proposes that such order amendments may also be made manually by a natural person who entered the order on behalf of the retail investor. Pursuant to proposed Interpretation and Policy .04, the purpose of the prohibition on changing the terms of an order in Exchange Rule 11.21(a)(2) is to prevent RMOs from utilizing algorithms that trade in a manner more appropriate for professional trading.[23]

The Exchange states that by routing Retail Orders to the Exchange, RMOs and their retail investors will benefit from the Exchange's retail-only pricing incentives, as well as increased price improvement opportunities and enhanced order priority offered by the Exchange's Retail Priority program.[24] In support of its proposal, the Exchange also states that it has in place robust protections to ensure only bona fide retail orders are designated as ''Retail Orders,'' and that the proposed amendments will augment the Exchange's existing RMO framework.[25]

[17] *Id.* at 10131. According to the Exchange, the term ''retail investor'' would not be intended to include individual investors that engage in more professional trading strategies designed to profit from bid-ask spreads, short-term price movements, and arbitrage, or in trading behavior where multiple buy and sell orders are entered over a short period of time based on market conditions. *Id.*

[18] *Id.*

[19] *Id.*

[20] *Id.* at 10132. The Exchange states that acceptable uses of algorithms by an RMO would include, but not be limited to: a smart order router to route the Retail Order to the Exchange for execution; a smart order router to assess trading venues for the best priced quotation and liquidity prior to routing the Retail Order to the Exchange; an order management system, smart order router, or other functionality to change the terms an order to seek a better execution price; use of an order management system to assist with portfolio rebalancing and asset reallocation for the accounts of retail investors; and a retail investor's use of automated investment management tools offered by RMOs to manage their assets based on their goals and risk tolerance (*i.e.,* robo-advisory solutions). *Id.*

[21] *Id.* at 10133. The Exchange states that examples of such algorithms would include, but not be limited to, algorithms developed for market-making, high-frequency trading, liquidity provision, arbitrage, hedging, or proprietary trading. In addition to the fact that such orders do not typically originate from a natural person, entities engaging in such trading strategies are not typically doing so for the account of a retail investor. *Id.*

[22] *Id. See also supra* note 15 describing the Exchange's proposed definition of Retail Order. The Exchange states that accordingly, an RMO may utilize an algorithm to add a limit price to an unpriced order, amend an order's price or size to manage an order's marketability or mitigate the risk of receiving executions at aberrant prices, or adjust the price or size of an order as market conditions or trading objectives may dictate. *See* Notice, *supra* note 5, at 10133.

[23] Proposed Interpretation and Policy .04 to Exchange Rule 11.21.

[24] *See* Notice, *supra* note 5, at 10136.

[25] *See id.* at 10134.

III. Proceedings To Determine Whether To Approve or Disapprove SR–CboeEDGX–2024–009, and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act[26] to determine whether the proposed rule change should be approved or disapproved. Institution of such proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide additional comment on the proposed rule change to inform the Commission's analysis of whether to approve or disapprove the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,[27] the Commission is providing notice of the grounds for disapproval under consideration. As described above, the Exchange has proposed to amend its definition of Retail Order and adopt related Interpretations and Policies describing: (1) the term ''retail investor'' as used therein, (2) the term ''natural person'' as used therein, (3) permissible uses of algorithms when entering Retail Orders onto the Exchange, and (4) when an RMO may amend a Retail Order's price or side. The Commission is instituting proceedings to allow for additional analysis of, and input from commenters with respect to, the proposed rule change's consistency with the Act, and in particular, Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest; and not be designed to permit unfair discrimination between customers, issuers, brokers or dealers.[28]

The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, which are set forth in the Notice, in addition to any other comments they may wish to submit about the proposed rule change. In particular, the Commission seeks

[26] 15 U.S.C. 78s(b)(2)(B).

[27] *Id.*

[28] 15 U.S.C. 78f(b)(5).

comment on the following questions and asks commenters to submit data where appropriate to support their views:

1. The Exchange states that it ''seeks to clarify precisely how Retail Orders may be entered onto the Exchange by RMOs through the use of algorithms.'' [29] What are commenters' views on whether the Exchange has described with sufficient clarity its proposed new definition of Retail Order and related Interpretations and Policies, including with respect to the circumstances under which (i) algorithms and computerized methodologies would be permitted for the submission of Retail Orders, and (ii) a Retail Member Organization would be permitted to change the terms of a Retail Order with respect to price and side, either manually or algorithmically? Why or why not?

2. The Exchange states that the proposed rule change will ''ensure that only bona fide retail orders are able to take advantage of the benefits provided to Retail Orders by the Exchange.'' [30] What are commenters' views on whether the proposed rule change would ensure that only bona fide retail orders benefit from retail-only incentives provided by the Exchange? What are commenters' views on whether the proposed rule change would enhance the ability of bona fide retail trading interest to compete for executions? [31] Why or why not?

IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their data, views, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposed rule change, is consistent with Sections 6(b)(5) or any other provision of the Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of data, views, and arguments, the Commission will consider, pursuant to Rule 19b–4 under the Act,[32] any request for an opportunity to make an oral presentation.[33]

Interested persons are invited to submit written data, views, and arguments regarding whether the proposed rule change should be approved or disapproved by June 7, 2024. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by June 21, 2024. The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, in addition to any other comments they may wish to submit about the proposed rule change.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeEDGX–2024–009 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–CboeEDGX–2024–009. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeEDGX–2024–009 and should be submitted by June 7, 2024. Rebuttal comments should be submitted by June 21, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–10823 Filed 5–16–24; 8:45 am]

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[29] *See* Notice, *supra* note 5, at 10135.

[30] *See* Notice, *supra* note 5, at 10135.

[31] In approving the Exchange's existing definition of Retail Order, the Commission stated that ''the Exchange's proposal represents a reasonable effort to enhance the ability of bona fide retail trading interest to compete for executions with orders entered by other market participants that may be better equipped to optimize their place in the intermarket queue.'' Retail Priority Approval Order, *supra* note 10, at 53791.

[32] 17 CFR 240.19b–4.

[33] Section 19(b)(2) of the Act, as amended by the Securities Acts Amendments of 1975, Public Law 94–29 (Jun. 4, 1975), grants to the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Acts Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

[34] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100116; File No. SR–BX–2024–014]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend its Fees for Connectivity and Co-location Services

May 13, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 29, 2024, Nasdaq BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes amend the Exchange's fees for connectivity and co-location services, as described further below.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/*

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

rulebook/bx/rules, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's fees relating to connectivity and co-location services.[3] Specifically, the Exchange proposes to raise its fees for connectivity and co-location services in General 8, fees assessed for remote multi-cast ITCH (''MITCH'') Wave Ports in Equity 7, Section 115, and certain fees related to its Testing Facilities in Equity 7, Section 130 by 5.5%, with certain exceptions.

General 8, Section 1 includes the Exchange's fees that relate to connectivity, including fees for cabinets, external telco/inter-cabinet connectivity fees, fees for connectivity to the Exchange, fees for connectivity to third party services, fees for market data connectivity, fees for cabinet power install, and fees for additional charges and services. General 8, Section 2 includes the Exchange's fees for direct connectivity services, including fees for direct circuit connection to the Exchange, fees for direct circuit connection to third party services, and fees for point of presence connectivity. With the exception of the Exchange's GPS Antenna fees and the Cabinet Proximity Option Fee for cabinets with power density >10kW,[4] the Exchange proposes to increase its fees throughout General 8 by 5.5%.

In addition to increasing fees in General 8, the Exchange also proposes to increase certain fees in Equity 7. First, the Exchange proposes to increase the installation and recurring monthly fees assessed for remote MITCH Wave Ports[5] in Equity 7, Section 115 by 5.5%. In addition, the Exchange proposes to increase certain fees in Section 130(d), which relate to the Testing Facility. Equity 7, Section 130(d)(2) provides that subscribers to the Testing Facility located in Carteret, New Jersey shall pay a fee of $1,000 per hand-off, per month for connection to the Testing Facility. The hand-off fee includes either a 1Gb or 10Gb switch port and a cross connect to the Testing Facility. In addition, Equity 7, Section 130(d)(2) provides that subscribers shall also pay a one-time installation fee of $1,000 per hand-off. The Exchange proposes to increase these aforementioned fees by 5.5% to require that subscribers to the Testing Facility shall pay a fee of $1,055 per hand-off, per month for connection to the Testing Facility and a one-time installation fee of $1,055 per hand-off.

The proposed increases in fees would enable the Exchange to maintain and improve its market technology and services. With the exception of fees that were established as part of a new service in 2017 (and have remained unchanged since their adoption), the Exchange has not increased any of the fees included in the proposal since 2015, and many of the fees date back to between 2010 and 2014. However, since 2015, there has been notable inflation. Between 2015 and 2024, the dollar had an average inflation rate of 2.97% per year, producing a cumulative price increase of 30.12%.[6] Notwithstanding inflation, the Exchange historically has not increased its fees every year.[7] The proposed fees represent a 5.5% increase from the current fees, which is far below inflation since 2015, which exceeded 30%.[8] In addition to being far below the cumulative inflation rate since 2015, the Exchange also believes that the proposed 5.5% increase is reasonable because it is comparable to recent inflation rates for one-year periods. For example, in 2023, the inflation rate was 4.12% and in 2022, the inflation rate was 8%.[9] The Exchange is sensitive to the sticker shock that would occur if the Exchange raised its fees by more than 30% and therefore proposes a more modest increase, similar to that of inflation in recent one-year periods.

The Exchange believes that it is reasonable to increase its fees to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2015. The Exchange notes that this inflationary effect is a general phenomenon that is independent of any change in the Exchange's costs in providing its goods and services. The Exchange believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects. The Exchange notes that other exchanges have filed for comparable or higher increases in certain connectivity-related fees, based in part on similar rationale.[10]

In addition, the Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding the Exchange's existing co-location facility to offer customers additional space and power. These investments, and the value they provide to customers, far exceed the amount of the proposed price increases. It is reasonable and consistent with the Act for the Commission to allow the Exchange to recoup these investments by charging fees, lest the Commission will disincentivize the Exchange to make similar investments in the future—a result that would be detrimental to the Exchange's competitiveness as well as the interests of market participants and investors.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b)

[3] The Exchange initially filed the proposed pricing change on March 1, 2024 (SR–BX–2024–008). The instant filing replaces SR–BX–2024–008, which was withdrawn on April 29, 2024.

[4] The Exchange proposes to exclude the GPS Antenna fees from the proposed fee increase because, unlike the other fees in General 8, the Exchange recently increased its GPS Antenna fees. *See* Securities Exchange Act Release No. 34–99124 (December 8, 2023), 88 FR 86715 (December 14, 2023) (SR–BX–2023–033). The Exchange also proposes to exclude the Cabinet Proximity Option Fee for cabinets with power density >10kW from the proposed fee increase because the Exchange recently established such fee. *See* Securities Exchange Act Release No. 34–99794 (March 20, 2024), 89 FR 21155 (March 26, 2024) (SR–BX–2024–010).

[5] Remote MITCH Wave Ports are for clients co-located at other third-party data centers, through which NASDAQ TotalView ITCH market data is distributed after delivery to those data centers via wireless network.

[6] *See https://www.officialdata.org/us/inflation/2015?amount=1* (Last updated February 27, 2024).

[7] Unregulated competitors providing connectivity and colocation services often have annual price increases written into their agreements with customers to account for inflation and rising costs.

[8] Between 2017 and 2024, inflation exceeded 25%. *See https://www.officialdata.org/us/inflation/2017?amount=1* (Last updated February 27, 2024).

[9] *See https://www.officialdata.org/us/inflation/2022?endYear=2023&amount=1.*

[10] *See, e.g.,* Securities Exchange Act Release No. 34–100004 (April 22, 2024), 89 FR 32465 (April 26, 2024) (SR–CboeBYX–2024–012).

of the Act,[11] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[12] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

This belief is based on a couple factors. First, the current fees do not properly reflect the value of the services and products, as fees for the services and products in question have been static in nominal terms, and therefore falling in real terms due to inflation. Second, exchange fees are constrained by the fact that market participants can choose among 16 different venues for equities trading and 17 different venues for options trading, and therefore no single venue can charge excessive fees for its products without losing customers and market share.

Real Exchange Fees Have Fallen

As explained above, with the exception of fees that were established as part of a new service in 2017 (and have remained unchanged since their adoption), the Exchange has not increased any of the fees included in the proposal since 2015, and many of the fees date back to between 2010 and 2014. This means that such fees have fallen in real terms due to inflation, which has been notable. Between 2015 and 2024, the dollar had an average inflation rate of 2.97% per year, producing a cumulative price increase of 30.12%.[13] Notwithstanding inflation, the Exchange historically has not increased its fees every year.[14] As noted above, the Exchange has not increased the fees in this proposal for over 8 years (or in the case of services introduced in 2017, for over 6 years since the services were introduced). Accordingly, the Exchange believes that the proposed fees are reasonable as they represent a 5.5% increase from the current fees, which is far below inflation since 2015, which exceeded 30%.[15] In addition to being far below the inflation rate since 2015, the Exchange also believes that the proposed 5.5% increase is reasonable because it is comparable to recent inflation rates for one-year periods. For example, in 2023, the inflation rate was 4.12% and in 2022, the inflation rate was 8%.[16] The Exchange is sensitive to the sticker shock that would occur if the Exchange raised its fees by more than 30% and therefore proposes a more modest increase, similar to that of inflation in recent one-year periods.

The Exchange believes that it is reasonable to increase its fees to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2015. The Exchange notes that this inflationary effect is a general phenomenon that is independent of any change in the Exchange's costs in providing its goods and services. The Exchange believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects.

In addition, the Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding the Exchange's existing co-location facility to offer customers additional space and power. Again, these investments, and the value they provide to customers, far exceed the amount of the proposed price increases. It is reasonable and consistent with the Act for the Commission to allow the Exchange to recoup these investments by charging fees, lest the Commission will disincentivize the Exchange to make similar investments in the future—a result that would be detrimental to the Exchange's competitiveness as well as the interests of market participants and investors.

Customers Have a Choice in Trading Venue

Customers face many choices in where to trade both equities and options. Market participants will continue to choose trading venues and the method of connectivity based on their specific needs. No broker-dealer is required to become a Member of the Exchange. There is no regulatory requirement that any market participant connect to any one exchange, nor that any market participant connect at a particular connection speed or act in a particular capacity on the Exchange, or trade any particular product offered on an exchange. Moreover, membership is not a requirement to participate on the Exchange. Indeed, the Exchange is unaware of any one exchange whose membership includes every registered broker-dealer. The Exchange also believes substitutable products and services are available to market participants, including, among other things, other equities and options exchanges that a market participant may connect to in lieu of the Exchange, indirect connectivity to the Exchange via a third-party reseller of connectivity, and/or trading of equities or options products within markets which do not require connectivity to the Exchange, such as the Over-the-Counter (OTC) markets.

There are currently 16 registered equities exchanges that trade equities and 17 exchanges offering options trading services. No single equities exchange has more than 15% of the market share.[17] No single options exchange trades more than 14% of the options market by volume and only one of the 17 options exchanges has a market share over 10 percent.[18] This broad dispersion of market share demonstrates that market participants can and do exercise choice in trading venues. Further, low barriers to entry mean that new exchanges may rapidly enter the market and offer additional substitute platforms to further compete with the Exchange and the products it offers.

As such, the Exchange must set its fees, including its fees for connectivity and co-location services and products, competitively. If not, customers may move to other venues or reduce use of the Exchange's services. ''If competitive forces are operative, the self-interest of the exchanges themselves will work powerfully to constrain unreasonable or unfair behavior.'' [19] Accordingly, ''the existence of significant competition provides a substantial basis for finding that the terms of an exchange's fee proposal are equitable, fair, reasonable, and not unreasonably or unfairly discriminatory.'' [20] Disincentivizing market participants from purchasing Exchange connectivity would only serve to discourage participation on the Exchange, which ultimately does not

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(4) and (5).

[13] *See https://www.officialdata.org/us/inflation/2015?amount=1* (Last updated February 27, 2024).

[14] As noted above, unregulated competitors providing connectivity and colocation services often have annual price increases written into their agreements with customers to account for inflation and rising costs.

[15] Between 2017 and 2024, inflation exceeded 25%. *See https://www.officialdata.org/us/inflation/2017?amount=1* (Last updated February 27, 2024).

[16] *See https://www.officialdata.org/us/inflation/2022?endYear=2023&amount=1.*

[17] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (Last updated January 11, 2024), available at *https://www.cboe.com/us/equities/market_statistics/.*

[18] *See* Nasdaq, Options Market Statistics (Last updated January 11, 2024), available at *https://www.nasdaqtrader.com/Trader.aspx?id=OptionsVolumeSummary.*

[19] *See* Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74,770 (December 9, 2008) (SR–NYSEArca–2006–21).

[20] *Id.*

benefit the Exchange. Moreover, if the Exchange charges excessive fees, it may stand to lose not only connectivity revenues but also other revenues, including revenues associated with the execution of orders.

In summary, the proposal represents an equitable allocation of reasonable dues, fees and other charges because Exchange fees have fallen in real terms and customers have a choice in trading venue and will exercise that choice and trade at another venue if exchange fees are not set competitively.

No Unfair Discrimination

The Exchange believes that the proposed fee changes are not unfairly discriminatory because the fees are assessed uniformly across all market participants that voluntarily subscribe to or purchase connectivity and co-location services or products, which are available to all customers.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Nothing in the proposal burdens inter-market competition (the competition among self-regulatory organizations) because approval of the proposal does not impose any burden on the ability of other exchanges to compete. The Exchange operates in a highly competitive market in which market participants can determine whether or not to connect to the Exchange based on the value received compared to the cost of doing so. Indeed, market participants have numerous alternative exchanges that they may participate on and direct their order flow, as well as off-exchange venues, where competitive products are available for trading.

Nothing in the proposal burdens intra-market competition (the competition among consumers) because the Exchange's connectivity and co-location services are available to any customer under the same fee schedule as any other customer, and any market participant that wishes to purchase such services can do so on a non-discriminatory basis.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[21]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–BX–2024–014 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–BX–2024–014. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–BX–2024–014 and should be submitted on or before June 7, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–10825 Filed 5–16–24; 8:45 am]

BILLING CODE 8011–01–P

[21] 15 U.S.C. 78s(b)(3)(A)(ii).

[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100109; File No. SR–PEARL–2024–22]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the MIAX Pearl Equities Exchange Fee Schedule To Establish Market Data Fees

May 13, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 30, 2024, MIAX PEARL, LLC (''MIAX Pearl'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the MIAX Pearl Equities Exchange Fee Schedule (the ''Fee Schedule'') to adopt fees for the Exchange's proprietary market data feeds.[3]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] All references to the ''Exchange'' in this filing refer to MIAX Pearl Equities. Any references to the

Continued

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxoptions.com/rule-filings,* at MIAX Pearl's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

MIAX Pearl Equities provided its proprietary market data for free to subscribers for over three and half years since it commenced operations in September 2020.[4] Prior to the initial proposal to adopt market data fees, the Exchange solely and entirely absorbed all costs associated with compiling and disseminating its proprietary market data. The Exchange offers two standard proprietary market data products, the Top of Market (''ToM'') feed and the Depth of Market (''DoM'') feed (collectively, the ''market data feeds''). Each of these proprietary market data products are described in Exchange Rule 2625.

Exchange Rule 2625(a) provides that the DoM feed is a data feed that contains the displayed price and size of each order in an equity security entered in the System,[5] as well as order execution information, order cancellations, order modifications, order identification numbers, and administrative messages. Exchange Rule 2625(b) provides that the ToM feed is a data feed that contains the price and aggregate size of displayed top of book quotations, order execution information, and administrative messages for equity securities entered into the System. Section 3 of the Fee Schedule entitled, Market Data Fees, specifically provides that fees for both the ToM and DoM feeds are waived for the Waiver Period.[6] As described in more detail below, the Exchange proposes to remove this waiver language and adopt fees for the ToM and DoM feeds to recoup its ongoing costs going forward.[7]

The Exchange notes that there is no requirement that any Equity Member [8] or market participant subscribe to the ToM or DoM feeds offered by the Exchange. Instead, an Equity Member may choose to maintain subscriptions to the ToM or DoM feeds based on their own business needs and trading models. The proposed fees will not apply differently based upon the size or type of firm, but rather based upon the subscriptions that each firm elects to purchase.

The Exchange commenced operations in September 2020 and expressly waived fees for both the ToM and DoM data feeds since that time to incentivize market participants to subscribe and make the Exchange's market data more widely available.[9] In the three and a half years since the Exchange launched operations, its market share has grown from 0% to approximately 2.0% for the month of March 2024.[10] One of the primary objectives of the Exchange is to provide competition and to provide low cost options to the industry. Consistent with this objective, the Exchange believes that this proposal reflects a simple, competitive, reasonable, and equitable pricing structure.

The Exchange believes that exchanges, in setting fees of all types, should meet very high standards of transparency to demonstrate why each new fee or fee increase meets the requirements of the Act that fees be reasonable, equitably allocated, not unfairly discriminatory, and not create an undue burden on competition among Equity Members and markets. The Exchange believes this high standard is especially important when an exchange imposes various fees for market participants to access an exchange's market data. The Exchange believes that it is important to demonstrate that these fees are based on its costs and reasonable business needs. Accordingly, the Exchange included a cost analysis below in connection with the proposed market data fees and the costs associated with compiling and providing the ToM and DoM feeds (''Cost Analysis'').

The Exchange believes the proposed fees will allow the Exchange to offset the expenses [11] the Exchange has and will continue to incur associated with compiling and disseminating the ToM and DoM feeds. Further, the Exchange believes it provided sufficient transparency in the Cost Analysis provided below, which provides a basis for how the Exchange determined to charge such fees. The Exchange's proposal is described below.

Definitions

The Exchange proposes to include a Definitions section at the beginning of Section 3 of the Fee Schedule. The purpose of the Definitions section is to provide market participants greater clarity and transparency regarding the applicability of fees by defining certain terms used in connection with market data feeds within the Fee Schedule in a single location related to the Exchange's market data products. The Exchange notes that other equities exchanges include similar Definitions in their respective fee schedules,[12] and that each of the Exchange's proposed definitions are based on those exchanges. The

options trading facility of MIAX PEARL, LLC will specifically be referred to as ''MIAX Pearl Options.''

[4] *See* Securities Exchange Act Release No. 90651 (December 11, 2020), 85 FR 81971 (December 17, 2020) (SR–PEARL–2020–33).

[5] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

[6] The term ''Waiver Period'' means, for each applicable fee, the period of time from the initial effective date of the MIAX Pearl Equities Fee Schedule until such time that MIAX Pearl has an effective fee filing establishing the applicable fee. MIAX Pearl Equities will issue a Regulatory Circular announcing the establishment of an applicable fee that was subject to a Waiver Period at least fifteen (15) days prior to the termination of the Waiver Period and effective date of any such applicable fee. *See* the Definitions section of the Fee Schedule.

[7] The Exchange initially filed the proposed fee change on March 26, 2024 for effectiveness on April 1, 2024. *See* Securities Exchange Act Release No. 99907 (April 4, 2024), 89 FR 25293 (April 10, 2024) (SR–PEARL–2024–15) (the ''Initial Proposal''). The Exchange withdrew SR–PEARL–2024–15 on April 30, 2024 and replaced it with this filing. The Exchange notes this filing proposes a reduced fee for Non-Display Usage by Trading Platforms for the ToM feed from $2,500 per month in the Initial Proposal to $1,000 per month. The reduced fee for Non-Display Usage by Trading Platforms will be effective May 1, 2024. All other proposed fees remain the same from the Initial Proposal. *See* Fee Change Alert—MIAX Pearl Equities Exchange—May 1, 2024, *available at https://www.miaxglobal.com/alert/2024/04/30/miax-pearl-equities-exchange-may-1-2024-fee-changes.*

[8] The term ''Equity Member'' is a Member authorized by the Exchange to transact business on MIAX Pearl Equities. *See* Exchange Rule 1901.

[9] *See supra* note 4.

[10] *See* the ''Market Share'' section of the Exchange's website, *available at https://www.miaxglobal.com/.*

[11] For the avoidance of doubt, all references to expense or costs in this filing, including the cost categories discussed below, refer to costs incurred by MIAX Pearl Equities only and not MIAX Pearl Options, the options trading facility.

[12] *See* the market data sections of the fee schedules for the Cboe BZX Exchange, Inc. (''Cboe BZX''); Cboe BYX Exchange, Inc. (''Cboe BYX''); Cboe EDGA Exchange, Inc. (''Cboe EDGA''); *and* Cboe EDGX Exchange, Inc. (''Cboe EDGX''). *See also* the market data definition section of the MEMX LLC's (''MEMX'') fee schedule; *and* Securities Exchange Act Release No. 97130 (March 13, 2023), 88 FR 16491 (March 17, 2023) (SR–MEMX–2023–04) (''MEMX Market Data Fee Proposal'').

Exchange believes that including a Definitions section for market data products makes the Fee Schedule more user-friendly and comprehensive.

The Exchange proposes to define the following terms in Section 3 of the Fee Schedule:

- *Distributor.* Any entity that receives the Exchange data product directly from the Exchange or indirectly through another entity and then distributes it internally or externally to a third party.
- *External Distributor.* A Distributor that receives the Exchange data product and then distributes that data to a third party or one or more Users outside the Distributor's own entity.
- *Internal Distributor.* A Distributor that receives the Exchange data product and then distributes that data to one or more Users within the Distributor's own entity.
  - The Exchange notes that it proposes to use the phrase ''own entity'' in the definition of Internal Distributor and External Distributor because a Distributor would be permitted to share data received from an exchange data product to other legal entities affiliated with the Distributor's entity that have been disclosed to the Exchange without such distribution being considered external to a third party. For instance, if a company has multiple affiliated broker-dealers under the same holding company, that company could have one of the broker-dealers or a non-broker-dealer affiliate subscribe to an exchange data product and then share the data with other affiliates that have a need for the data. This sharing with affiliates would not be considered external distribution to a third party but instead would be considered internal distribution to data recipients within the Distributor's own entity.
- *Non-Display Usage.* Any method of accessing an Exchange data product that involves access or use by a machine or automated device without access or use of a display by a natural person or persons.
- *Non-Professional User.* A natural person or qualifying trust that uses Exchange data only for personal purposes and not for any commercial purpose and, for a natural person who works in the United States, is not: (i) registered or qualified in any capacity with the Securities and Exchange Commission, the Commodities Futures Trading Commission, any state securities agency, any securities exchange or association, or any commodities or futures contract market or association; (ii) engaged as an ''investment adviser'' as that term is defined in Section 202(a)(11) of the Investment Advisors Act of 1940 (whether or not registered or qualified under that Act); or (iii) employed by a bank or other organization exempt from registration under federal or state securities laws to perform functions that would require registration or qualification if such functions were performed for an organization not so exempt; or, for a natural person who works outside of the United States, does not perform the same functions as would disqualify such person as a Non-Professional User if he or she worked in the United States.
- *Professional User.* Any User other than a Non-Professional User.
- Trading Platform. Any execution platform operated as or by a registered National Securities Exchange (as defined in Section 3(a)(1) of the Exchange Act), an Alternative Trading System (as defined in Rule 300(a) of Regulation ATS), or an Electronic Communications Network (as defined in Rule 600(b)(23) of Regulation NMS).
- *User.* A Professional User or Non-Professional User.

Proposed Market Data Pricing

As described above, the ToM feed is a data feed that contains the price and aggregate size of displayed top of book quotations, order execution information, and administrative messages for equity securities entered into the System. The DoM feed is a data feed that contains the displayed price and size of each order in an equity security entered in the System, as well as order execution information, order cancellations, order modifications, order identification numbers, and administrative messages. The Exchange proposes to charge the below fees for the ToM and DoM data feeds, which, the Exchange believes are generally similar to or lower than market data fees charged by other similarly situated equities exchanges. Each of the below capitalized terms are defined above and would be included under the proposed Definitions section under Section 3, Market Data Fees, of the Fee Schedule.

1. *Internal Distributor Fee.* The Exchange proposes to charge Internal Distributors a monthly fee of $1,000.00 for the ToM feed and $2,000.00 for the DoM feed. The proposed Internal Distributor fees would only be charged once per month per Distributor.

2. *External Distributor Fee.* The Exchange proposes to charge External Distributors a monthly fee of $2,000.00 for the ToM feed and $2,500.00 for the DoM feed. The proposed External Distributor fees would only be charged once per month per Distributor.

3. *User Fees.* For the ToM feed, the Exchange proposes to charge a monthly fee of $2.00 for each Professional User and $0.10 for each Non-Professional User. For the DoM feed, the Exchange proposes to charge a monthly fee of $30.00 for each Professional User and $3.00 for each Non-Professional User. The proposed User fees would apply to each person that has access to the ToM or DoM feed that is provided by a Distributor (either Internal or External) for displayed usage. Each Distributor's User count would include every individual that accesses the data regardless of the purpose for which the individual uses the data. Distributors of the ToM or DoM feed would be required to report all Professional and Non-Professional Users in accordance with the following:

- In connection with a Distributor's distribution of the ToM or DoM feed, the Distributor must count as one User each unique User that the Distributor has entitled to have access to the ToM or DoM feed.
- Distributors must report each unique individual person who receives access through multiple devices or multiple methods (*e.g.,* a single User has multiple passwords and user identifications) as one User.
- If a Distributor entitles one or more individuals to use the same device, the Distributor must include only the individuals, and not the device, in the count. Thus, Distributors would not be required to report User device counts associated with a User's display use of the data feed.

4. *Enterprise Fee.* As an alternative to User fees, Distributors may purchase a monthly Enterprise license to receive ToM or DoM feeds for distribution to an unlimited number of Professional and Non-Professional Users. This provision would be codified under footnote ''a'' under the description of each the ToM and DoM feed in the Fee Schedule. The Exchange proposes to establish a monthly Enterprise fee of $15,000.00 for ToM and $25,000.00 for the DoM feed.

5. *Non-Display Usage Fees.* For both the ToM and DoM feeds, the Exchange proposes to establish separate Non-Display Usage fees for usage by Trading Platforms and other Users (*i.e.,* not by Trading Platforms).

- *Non-Display Usage.* For Non-Display Usage, the Exchange proposes to establish a monthly fee of $1,000.00 for the ToM feed and $2,500.00 for the DoM feed.[13]

[13] Non-Display Usage would include trading uses such as high frequency or algorithmic trading as well as any trading in any asset class, automated order or quote generation and/or order pegging, price referencing for smart order routing, operations control programs, investment analysis, order

Continued

• Distributors of Non-Display Usage for both the ToM and DoM feed will only be subject to the Non-Display Usage fee for the DoM feed. In other words, such Distributors would receive both the ToM and DoM feeds but only be charged the Non-Display Usage fee of $2,500.00 for the DoM feed. This provision would be codified under footnote ''b'' under the description of each the ToM and DoM feed in the Fee Schedule.

• *Non-Display Usage by Trading Platforms.* For Non-Display Usage by Trading Platforms, the Exchange proposes to establish a monthly fee of $1,000.00 for the ToM feed and $2,500.00 for the DoM feed. The Non-Displayed Usage by Trading Platform fee would only be charged per Distributor that uses the data within a Trading Platform.

• Distributors of Non-Display Usage by Trading Platforms for both the ToM and DoM feed will only be subject to the Non-Display Usage by Trading Platforms fee for the DoM feed. In other words, such Distributors would receive both the ToM and DoM feeds but only be charged the Non-Display Usage by Trading Platforms fee of $2,500.00 for the DoM feed. This provision would be codified under footnote ''c'' under the description of each the ToM and DoM feed in the Fee Schedule.

• The fee would also represent the maximum charge per Distributor regardless of the number of Trading Platforms operated by the Distributor that receives the data for Non-Display Usage. This provision would be codified under footnote ''d'' under the description of each the ToM and DoM feed in the Fee Schedule.

• *Miscellaneous.* The proposed fees for Non-Display Usage would only be charged once per category per Distributor. In other words, with respect to Non-Display Usage Fees, a Distributor that uses the ToM feed for: (i) non-display purposes but not to operate a Trading Platform would pay $1,000.00 per month; (ii) a Distributor that uses the ToM feed in connection with the operation of one or more Trading Platforms (but not for other purposes) would pay $2,500.00 per month; and (iii) a Distributor that uses the ToM feed for non-display purposes other than operating a Trading Platform and for the operation of one or more Trading Platforms would pay $3,500.00 per month.

verification, surveillance programs, risk management, compliance, and portfolio management.

Implementation

The Exchange issued alerts publicly announcing the proposed fees on January 31, 2024 and March 15, 2024.[14] The Exchange issued a Regulatory Circular on March 15, 2024 announcing the establishment of the proposed market data fees to satisfy the required fifteen (15) day notice period, as described in the Definitions Section of the Fee Schedule for termination of the Waiver Period.[15]

The proposed reduced monthly fee for ToM for Non-Display Usage by Trading Platform will be effective beginning May 1, 2024. The remaining fees subject to this proposal are immediately effective.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6(b)[16] of the Act in general, and furthers the objectives of Section 6(b)(4)[17] of the Act, in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Equity Members and other persons using its facilities. Additionally, the Exchange believes that the proposed fees are consistent with the objectives of Section 6(b)(5)[18] of the Act in that they are designed 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 a free and open market and national market system, and, in general, to protect investors and the public interest, and, particularly, are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In 2019, Commission staff published guidance suggesting the types of information that self-regulatory organizations (''SROs'') may use to demonstrate that their fee filings comply with the standards of the Exchange Act (the ''Staff Guidance'').[19] While the Exchange understands that the Staff Guidance does not create new legal obligations on SROs, the Staff Guidance is consistent with the Exchange's view about the type and level of transparency that exchanges should meet to demonstrate compliance with their existing obligations when they seek to charge new fees. The Staff Guidance provides that in assessing the reasonableness of a fee, the Staff would consider whether the fee is constrained by significant competitive forces. To determine whether a proposed fee is constrained by significant competitive forces, the Staff Guidance further provides that the Staff would consider whether the evidence provided by an SRO in a Fee Filing proposal demonstrates (i) that there are reasonable substitutes for the product or service that is the subject of a proposed fee; (ii) that ''platform'' competition constrains the fee; and/or (iii) that the revenue and cost analysis provided by the SRO otherwise demonstrates that the proposed fee would not result in the SRO taking supra-competitive profits.[20] The Exchange provides sufficient evidence below to support the findings that the proposed fees are reasonable because the projected revenue and cost analysis contained herein demonstrates that the proposed fees would not result in the Exchange taking supra-competitive profits.

Cost Analysis

In general, the Exchange believes that exchanges, in setting fees of all types, should meet high standards of transparency to demonstrate why each new fee or fee increase meets the Exchange Act requirements that fees be reasonable, equitably allocated, not unfairly discriminatory, and not create an undue burden on competition among members and markets. In particular, the Exchange believes that each exchange should take extra care to be able to demonstrate that these fees are based on its costs and reasonable business needs.

Accordingly, in proposing to charge fees for market data, the Exchange is especially diligent in assessing those fees in a transparent way against its own aggregate costs of providing the related service, and in carefully and transparently assessing the impact on Equity Members—both generally and in relation to other Equity Members—to ensure the fees will not create a financial burden on any participant and

[14] *See* Fee Change Alert, MIAX Pearl Equities Exchange—April 1, 2024 Market Data Fee Changes, *available at https://www.miaxglobal.com/alert/2024/01/31/miax-pearl-equities-exchange-april-1-2024-market-data-fee-changes; see also* Fee Change Alert, MIAX Pearl Equities Exchange—Update: April 1, 2024 Market Data Fee Changes, available at *https://www.miaxglobal.com/alert/2024/03/15/miax-pearl-equities-exchange-update-april-1-2024-market-data-fee-changes.*

[15] *See* MIAX Pearl Equities Regulatory Circular 2024–06, Termination of Waiver Period for Market Data Fees and Establishment of Fee Amounts, dated March 15, 2024, *available at Pearl_Equities_RC_2024_06.pdf (miaxglobal.com).*

[16] 15 U.S.C. 78f.

[17] 15 U.S.C. 78f(b)(4).

[18] 15 U.S.C. 78f(b)(5).

[19] *See* Staff Guidance on SRO Rule Filings Relating to Fees (May 21, 2019), *available at https://www.sec.gov/tm/staff-guidance-sro-rule-filings-fees.*

[20] *Id.*

will not have an undue impact in particular on smaller Equity Members and competition among Equity Members in general. The Exchange does not believe it needs to otherwise address questions about market competition in the context of this filing because the proposed fees are consistent with the Act based on its Cost Analysis. The Exchange also believes that this level of diligence and transparency is called for by the requirements of Section 19(b)(1) under the Act,[21] and Rule 19b–4 thereunder,[22] with respect to the types of information SROs should provide when filing fee changes, and Section 6(b) of the Act,[23] which requires, among other things, that exchange fees be reasonable and equitably allocated,[24] not designed to permit unfair discrimination,[25] and that they not impose a burden on competition not necessary or appropriate in furtherance of the purposes of the Act.[26] This proposal addresses those requirements, and the analysis and data in this section are designed to clearly and comprehensively show how they are met.

In 2020, the Exchange completed a study of its aggregate costs to produce market data and connectivity, defined above as its Cost Analysis.[27] The Cost Analysis required a detailed analysis of the Exchange's aggregate baseline costs, including a determination and allocation of costs for core services provided by the Exchange—transaction execution, market data, membership services, physical connectivity, and port access (which provide order entry, cancellation and modification functionality, risk functionality, the ability to receive drop copies, and other functionality). The Exchange separately divided its costs between those costs necessary to deliver each of these core services, including infrastructure, software, human resources (*i.e.,* personnel), and certain general and administrative expenses (''cost drivers'').

As an initial step, the Exchange determined the total cost for the Exchange and its affiliated markets [28] for each cost driver as part of its 2024 budget review process. The 2024 budget review is a company-wide process that occurs over the course of many months, includes meetings among senior management, department heads, and the Finance Team. Each department head is required to send a ''bottom up'' budget to the Finance Team allocating costs at the profit and loss account and vendor levels for the Exchange and its affiliated markets based on a number of factors, including server counts, additional hardware and software utilization, current or anticipated functional or non-functional development projects, capacity needs, end-of-life or end-of-service intervals, number of members, market model (*e.g.,* price time or pro-rata, simple only or simple and complex markets, auction functionality, etc.), which may impact message traffic, individual system architectures that impact platform size,[29] storage needs, dedicated infrastructure versus shared infrastructure allocated per platform based on the resources required to support each platform, number of available connections, and employees allocated time. All of these factors result in different allocation percentages among the Exchange and its affiliated markets, *i.e.,* the different percentages of the overall cost driver allocated to the Exchange and its affiliated markets will cause the dollar amount of the overall cost allocated among the Exchange and its affiliated markets to also differ. Because the Exchange's parent company currently owns and operates four separate and distinct marketplaces, the Exchange must determine the costs associated with each actual market—as opposed to the Exchange's parent company simply concluding that all costs drivers are the same at each individual marketplace and dividing total cost by four (4) (evenly for each marketplace). Rather, the Exchange's parent company determines an accurate cost for each marketplace, which results in different allocations and amounts across exchanges for the same cost drivers, due to the unique factors of each marketplace as described above. This allocation methodology also ensures that no cost would be allocated twice or double-counted between the Exchange and its affiliated markets. MIAX PEARL, LLC further confirms that there is no double counting of expenses between the options and equities platform of MIAX PEARL, LLC. The Finance Team then consolidates the budget and sends it to senior management, including the Chief Financial Officer and Chief Executive Officer, for review and approval. Next, the budget is presented to the Board of Directors and the Finance and Audit Committees for each exchange for their approval. The above steps encompass the first step of the cost allocation process.

The next step involves determining what portion of the cost allocated to the Exchange pursuant to the above methodology is to be allocated to each core service, *e.g.,* connectivity and ports, market data, and transaction services. The Exchange and its affiliated markets adopted an allocation methodology with thoughtful and consistently applied principles to guide how much of a particular cost amount allocated to the Exchange should be allocated within the Exchange to each core service. This is the final step in the cost allocation process and is applied to each of the cost drivers set forth below. For instance, fixed costs that are not driven by client activity (*e.g.,* message rates), such as data center costs, were allocated more heavily to the provision of physical connectivity (for example, 60.1% of the data center total expense amount is allocated to 10Gb ULL connectivity), with smaller allocations to ToM and DoM (2.0% combined), and the remainder to the provision of other connectivity, ports, transaction execution, and membership services (37.9%). This next level of the allocation methodology at the individual exchange level also took into account factors similar to those set forth under the first step of the allocation methodology process described above, to determine the appropriate allocation to connectivity or market data versus allocations for other services. This allocation methodology was developed through an assessment of costs with senior management intimately familiar with each area of the Exchange's operations. After adopting this allocation methodology, the Exchange then applied an allocation of each cost driver to each core service, resulting in the cost allocations described below.[30] Each of the below cost allocations is unique to the Exchange and represents a percentage of overall cost that was allocated to the Exchange pursuant to the initial allocation described above.

[21] 15 U.S.C. 78s(b)(1).

[22] 17 CFR 240.19b–4.

[23] 15 U.S.C. 78f(b).

[24] 15 U.S.C. 78f(b)(4).

[25] 15 U.S.C. 78f(b)(5).

[26] 15 U.S.C. 78f(b)(8).

[27] The Exchange frequently updates it Cost Analysis as strategic initiatives change, costs increase or decrease, and market participant needs and trading activity changes. The Exchange's most recent Cost Analysis was conducted ahead of this filing.

[28] The affiliated markets include Miami International Securities Exchange, LLC (''MIAX''); separately, the options and equities markets of MIAX Pearl; and MIAX Emerald, LLC (''MIAX Emerald'').

[29] For example, MIAX maintains 24 matching engines, MIAX Pearl Options maintains 12 matching engines, MIAX Pearl Equities maintains 24 matching engines, and MIAX Emerald maintains 12 matching engines.

[30] The Exchange only offers two market data feeds, ToM and DoM. Therefore each cost allocation described below applies to market data generally since they are the only two data feeds the Exchange offers and are the subject of this proposal.

By allocating segmented costs to each core service, the Exchange was able to estimate by core service the potential margin it might earn based on different fee models. The Exchange notes that as a non-listing venue it has five primary sources of revenue that it can potentially use to fund its operations: transaction fees, fees for connectivity and port services, membership fees, regulatory fees, and market data fees. Accordingly, the Exchange must cover its expenses from these five primary sources of revenue. The Exchange also notes that as a general matter each of these sources of revenue is based on services that are interdependent. For instance, the Exchange's system for executing transactions is dependent on physical hardware and connectivity; only Equity Members and parties that they sponsor to participate directly on the Exchange may submit orders to the Exchange; many Equity Members (but not all) consume market data from the Exchange in order to trade on the Exchange; and, the Exchange consumes market data from external sources in order to comply with regulatory obligations. Accordingly, given this interdependence, the allocation of costs to each service or revenue source required judgment of the Exchange and was weighted based on estimates of the Exchange that the Exchange believes are reasonable, as set forth below. While there is no standardized and generally accepted methodology for the allocation of an exchange's costs, the Exchange's methodology is the result of an extensive review and analysis and will be consistently applied going forward for any other cost-justified potential fee proposals. In the absence of the Commission attempting to specify a methodology for the allocation of exchanges' interdependent costs, the Exchange will continue to be left with its best efforts to attempt to conduct such an allocation in a thoughtful and reasonable manner.

Through the Exchange's extensive Cost Analysis, which was again recently further refined, the Exchange analyzed nearly every expense item in the Exchange's general expense ledger to determine whether each such expense relates to the provision of market data feeds, and, if such expense did so relate, what portion (or percentage) of such expense actually supports the provision of market data feeds, and thus bears a relationship that is, ''in nature and closeness,'' directly related to market data feeds. In turn, the Exchange allocated certain costs more to physical connectivity and others to ports, while certain costs were only allocated to such services at a very low percentage or not at all, using consistent allocation methodologies as described above. Based on this analysis, the Exchange estimates that the aggregate monthly cost to provide the market data feeds is $150,031 (the Exchange divided the annual cost for each market data feed by 12 months, then added both numbers together), as further detailed below.

Costs Related to Offering the Market Data Feeds

The following chart details the individual line-item (annual) costs considered by the Exchange to be related to offering the market data feeds to its Equity Members and other customers, as well as the percentage of the Exchange's overall costs that such costs represent for such area (*e.g.,* as set forth below, the Exchange allocated approximately 8.9% of its overall Human Resources cost to offering the market data feeds).

Cost drivers	Allocated annual cost [a]	Allocted monthly cost [b]	% of all
Human Resources	$1,577,592	$131,466	8.9
Connectivity (external fees, cabling, switches, etc.)	933	78	2.0
Internet Services and External Market Data	0.00	0.00	0.0
Data Center	42,717	3,560	2.0
Hardware and Software Maintenance & Licenses	25,921	2,160	2.0
Depreciation	25,542	2,129	0.5
Allocated Shared Expenses	127,655	10,638	2.0
Total	1,800,360	150,031	5.1

[a] The Annual Cost includes figures rounded to the nearest dollar.
[b] The Monthly Cost was determined by dividing the Annual Cost for each line item by twelve (12) months and rounding up or down to the nearest dollar.

Below are additional details regarding each of the line-item costs considered by the Exchange to be related to offering the market data feeds. While some costs were attempted to be allocated as equally as possible among the Exchange and its affiliated markets, the Exchange notes that some of its cost allocation percentages for certain cost drivers differ when compared to the same cost drivers for the Exchange's affiliated markets, MIAX and MIAX Emerald, in their recent proposed fee changes for options market data.[31] This is because the Exchange's cost allocation methodology utilizes the actual projected costs of the Exchange (which are specific to the Exchange and are independent of the costs projected and utilized by the Exchange's affiliated markets) to determine its actual costs, which may vary across the Exchange and its affiliated markets based on factors that are unique to each marketplace, including that the Exchange, MIAX Pearl Options, and its affiliates trade different asset classes.

Human Resources

The Exchange notes that it and its affiliated markets anticipate that by year-end 2024, there will be 289 employees (excluding employees at non-options/equities exchange subsidiaries of Miami International Holdings, Inc. (''MIH''), the holding company of the Exchange and its affiliated markets), and each department leader has direct knowledge of the time spent by each employee with respect to the various tasks necessary to operate the Exchange. Specifically, twice a year, and as needed with additional new hires and new project initiatives, in consultation with employees as needed, managers and department heads assign

[31] *See* Securities Exchange Act Release Nos. 99736 (March 14, 2024), 89 FR 19929 (March 20, 2024) (SR–MIAX–2024–13) *and* 99737 (March 14, 2024), 89 FR 19915 (March 20, 2024) (SR–EMERALD–2024–09). *See also* SR–MIAX–2024–25 (filed April 23, 2024) and SR–EMERALD–2024–15 (filed April 18, 2024). For example, the overall portion of Human Resource costs allocated in this proposal is higher than the recent market data proposals filed by MIAX and MIAX Emerald due to their ability to leverage the same employees for options market data because they trade the same asset class, options. The Exchange is unable to do the same because it trades a different asset class, equities, which requires dedicated employees and systems.

a percentage of time to every employee and then allocate that time amongst the Exchange and its affiliated markets to determine each market's individual Human Resources expense. Then, managers and department heads assign a percentage of each employee's time allocated to the Exchange into buckets including network connectivity, ports, market data, and other exchange services. This process ensures that every employee is 100% allocated, ensuring there is no double counting between the Exchange and its affiliated markets.

For personnel costs (Human Resources), the Exchange calculated an allocation of employee time for employees whose functions include providing and maintaining market data feeds and performance thereof (primarily the Exchange's network infrastructure team, which spends a portion of their time performing functions necessary to provide market data). As described more fully above, the Exchange's parent company allocates costs to the Exchange and its affiliated markets and then a portion of the Human Resources costs allocated to the Exchange is then allocated to market data. From that portion allocated to the Exchange that applied to market data, the Exchange then allocated a weighted average of 9.1% of each employee's time from the above group to market data feeds (which excludes an allocation for the recently hired Head of Data Services for the Exchange and its affiliates).

The Exchange also allocated Human Resources costs to provide the market data feeds to a limited subset of personnel with ancillary functions related to establishing and maintaining such market data feeds (such as information security, sales, membership, and finance personnel). The Exchange allocated cost on an employee-by-employee basis (*i.e.,* only including those personnel who support functions related to providing market data feeds) and then applied a smaller allocation to such employees' time to market data (a weighted average of 8.8%, which includes an allocation for the Head of Data Services). This other group of personnel with a smaller allocation of Human Resources costs also have a direct nexus to providing the market data feeds, whether it is a sales person selling a market data feed, finance personnel billing for market data feeds or providing budget analysis, or information security ensuring that such market data feeds are secure and adequately defended from an outside intrusion.

The estimates of Human Resources cost were therefore determined by consulting with such department leaders, determining which employees are involved in tasks related to providing market data feeds, and confirming that the proposed allocations were reasonable based on an understanding of the percentage of time such employees devote to those tasks. This includes personnel from the Exchange departments that are predominately involved in providing the market data feeds: Business Systems Development, Trading Systems Development, Systems Operations and Network Monitoring, Network and Data Center Operations, Listings, Trading Operations, and Project Management. Again, the Exchange allocated a weighted average of 9.1% of each of their employee's time assigned to the Exchange for the market data feeds, as stated above. Employees from these departments perform numerous functions to support the market data feeds, such as the configuration and maintenance of the hardware necessary to support the market data feeds. This hardware includes servers, routers, switches, firewalls, and monitoring devices. These employees also perform software upgrades, vulnerability assessments, remediation and patch installs, equipment configuration and hardening, as well as performance and capacity management. These employees also engage in research and development analysis for equipment and software supporting market data feeds and design, and support the development and on-going maintenance of internally-developed applications as well as data capture and analysis, and Equity Member and internal Exchange reports related to network and system performance. The above list of employee functions is not exhaustive of all the functions performed by Exchange employees to support market, but illustrates the breath of functions those employees perform in support of the above cost and time allocations.

Lastly, the Exchange notes that senior level executives' time was only allocated to the market data feeds related Human Resources costs to the extent that they are involved in overseeing tasks related to providing market data. The Human Resources cost was calculated using a blended rate of compensation reflecting salary, equity and bonus compensation, benefits, payroll taxes, and 401(k) matching contributions.

Connectivity (External Fees, Cabling, Switches, etc.)

The Connectivity cost driver includes cabling and switches required to generate and disseminate the market data feeds and operate the Exchange. The Connectivity cost driver is more narrowly focused on technology used to complete Equity Member subscriptions to the market data feeds and the servers used at the Exchange's primary and back-up data centers specifically for the market data feeds. Further, as certain servers are only partially utilized to generate and disseminate the market data feeds, only the percentage of such servers devoted to generating and disseminating the market data feeds was included (*i.e.,* the capacity of such servers allocated to the market data feeds).[32]

Internet Services and External Market Data

The next cost driver consists of internet services and external market data. Internet services includes third-party service providers that provide the internet, fiber and bandwidth connections between the Exchange's networks, primary and secondary data centers, and office locations in Princeton and Miami. External market data includes fees paid to third parties, including other exchanges, to receive market data. The Exchange did not allocate any costs associated with internet services or external market data to the market data feeds.

Data Center

Data Center costs includes an allocation of the costs the Exchange incurs to provide the market data feeds in the third-party data centers where it maintains its equipment (such as dedicated space, security services, cooling and power). The Exchange does not own the primary data center or the secondary data center, but instead leases space in data centers operated by third parties. As the Data Center costs are primarily for space, power, and cooling of servers, the Exchange allocated 2.0% to the applicable Data Center costs for the market data feeds. The Exchange believes it is reasonable to apply the same proportionate percentage of Data

[32] The Exchange understands that the Investors Exchange, Inc. (''IEX'') and MEMX LLC (''MEMX'') both allocated a percentage of their servers to the production and dissemination of market data to support proposed market data fees. *See* Securities Exchange Act Release Nos. 94630 (April 7, 2022), 87 FR 21945, at page 21949 (April 13, 2022) (SR–IEX–2022–02) *and* 97130 (March 13, 2023), 88 FR 16491 (March 17, 2023) (SR–MEMX–2023–04). The Exchange does not have insight into either MEMX's or IEX's technology infrastructure or what their determinations were based on. However, the Exchange reviewed its own technology infrastructure and believes based on its design, it is more appropriate for the Exchange to allocate a portion of its Connectivity cost driver to market data based on a percentage of overall cost, not on a per server basis.

Center costs to that of the Connectivity cost driver.

Hardware and Software Maintenance and Licenses

Hardware and Software Maintenance and Licenses includes hardware and software licenses used to operate and monitor physical assets necessary to offer the market data feeds.[33] Because the hardware and software license fees are correlated to the servers used by the Exchange, the Exchange again applied an allocation of 2.0% of its costs for Hardware and Software Maintenance and Licenses to the market data feeds. The Exchange notes that this allocation may differ from its affiliates because MIAX Pearl Equities maintains software licenses that are unique to its trading platform and used only for the trading of equity securities. The cost for these licenses cannot be shared with MIAX Pearl Equities' affiliated options markets because each of those platforms trade only options, not equities. MIAX Pearl Equities' affiliates are able to share the cost of many of their software licenses among the multiple options platforms (thus lowering the cost to each individual options platform), whereas MIAX Pearl Equities cannot share such cost and, therefore, bears the entire cost.

Depreciation

All physical assets, software, and hardware used to provide the market data feeds, which also includes assets used for testing and monitoring of Exchange infrastructure to provide market data, were valued at cost, and depreciated or leased over periods ranging from three to five years. Thus, the depreciation cost primarily relates to servers necessary to operate the Exchange, some of which are owned by the Exchange and some of which are leased by the Exchange in order to allow efficient periodic technology refreshes.

The vast majority of the software the Exchange uses for its operations to generate and disseminate the market data feeds has been developed in-house over an extended period. This software development also requires quality assurance and thorough testing to ensure the software works as intended. The Exchange also included in the Depreciation cost driver certain budgeted improvements that the Exchange intends to capitalize and depreciate with respect to the market data feeds in the near-term. As with the other allocated costs in the Exchange's updated Cost Analysis, the Depreciation cost was therefore narrowly tailored to depreciation related to the market data feeds. As noted above, the Exchange allocated 0.5% of its allocated depreciation costs to providing the market data feeds.

This allocation is also based on MIAX Pearl Equities being a newer market and having newer physical assets and software subject to depreciation than its affiliate options exchanges. The Exchange's affiliate options exchanges are older markets that have more software and equipment that have been fully depreciated when compared to the newer software and hardware currently being depreciated by MIAX Pearl Equities at higher rates.

Allocated Shared Expenses

Finally, as with other exchange products and services, a portion of general shared expenses was allocated to the provision of the market data feeds. These general shared costs are integral to exchange operations, including its ability to provide the market data feeds. Costs included in general shared expenses include office space and office expenses (*e.g.,* occupancy and overhead expenses), utilities, recruiting and training, marketing and advertising costs, professional fees for legal, tax and accounting services (including external and internal audit expenses), and telecommunications. Similarly, the cost of paying directors to serve on the Exchange's Board of Directors is also included in the Exchange's general shared expense cost driver.[34] These general shared expenses are incurred by the Exchange's parent company, MIH, as a direct result of operating the Exchange and its affiliated markets.

The Exchange employed a process to determine a reasonable percentage to allocate general shared expenses to the market data feeds pursuant to its multi-layered allocation process. First, general expenses were allocated among the Exchange and affiliated markets as described above. Then, the general shared expense assigned to the Exchange was allocated across core services of the Exchange, including market data. Then, these costs were further allocated to sub-categories within the final categories, *i.e.,* the market data feeds as sub-categories of market data. In determining the percentage of general shared expenses allocated to market data that ultimately apply to the market data feeds, the Exchange looked at the percentage allocations of each of the cost drivers and determined a reasonable allocation percentage. The Exchange also held meetings with senior management, department heads, and the Finance Team to determine the proper amount of the shared general expense to allocate to the market data feeds. The Exchange, therefore, believes it is reasonable to assign an allocation, in the range of allocations for other cost drivers, while continuing to ensure that this expense is only allocated once. Again, the general shared expenses are incurred by the Exchange's parent company as a result of operating the Exchange and its affiliated markets and it is therefore reasonable to allocate a percentage of those expenses to the Exchange and ultimately to specific product offerings such as the market data feeds.

Again, a portion of all shared expenses were allocated to the Exchange (and its affiliated markets) which, in turn, allocated a portion of that overall allocation to all market data products offered by the Exchange. The Exchange then allocated 2.0% of the portion allocated to market data. The Exchange believes this allocation percentage is reasonable because, while the overall dollar amount may be higher than other cost drivers, the 2.0% is based on and in line with the percentage allocations of each of the Exchange's other cost drivers. The percentage allocated to the market data feeds also reflects its importance to the Exchange's strategy and necessity towards the nature of the Exchange's overall operations, which is to provide a resilient, highly deterministic trading system that relies on faster market data feeds than the Exchange's competitors to maintain premium performance. This allocation reflects the Exchange's focus on providing and maintaining high performance market data services, of which the market data feeds are main contributors.

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Cost Analysis—Additional Discussion

In conducting its Cost Analysis, the Exchange did not allocate any of its expenses in full to any core service (including market data) and did not double-count any expenses. Instead, as described above, the Exchange allocated

[33] This expense may differ from the Exchange's affiliated markets. This is because each market may maintain and utilize a different amount of hardware and software based on its market model and infrastructure needs. The Exchange allocated a percentage of the overall cost based on actual amounts of hardware and software utilized by that market, which resulted in different cost allocations and dollar amounts.

[34] The Exchange notes that MEMX allocated a precise amount of 10% of the overall cost for directors in a similar non-transaction fee filing. *See* Securities Exchange Act Release No. 97130 (March 13, 2023), 88 FR 16491 (March 17, 2023) (SR–MEMX–2023–04). The Exchange does not calculate is expenses at that granular a level. Instead, director costs are included as part of the overall general allocation.

applicable cost drivers across its core services and used the same Cost Analysis to form the basis of this proposal and the filings the Exchange recently submitted proposing fees for certain connectivity and ports offered by the Exchange. For instance, in calculating the Human Resources expenses to be allocated to market data based upon the above described methodology, the Exchange has a team of employees dedicated to network infrastructure and with respect to such employees the Exchange allocated network infrastructure personnel with a high percentage of the cost of such personnel (9.1%) given their focus on functions necessary to provide market data and the remaining 90.9% was allocated to connectivity services, port services, transaction services, and membership services. The Exchange did not allocate any other Human Resources expense for providing market data to any other employee group, outside of a smaller allocation of 8.8% for the market data feeds of the cost associated with certain specified personnel who work closely with and support network infrastructure personnel.

In total, the Exchange allocated 8.9% of its personnel costs (Human Resources) to providing the market data feeds. In turn, the Exchange allocated the remaining 91.1% of its Human Resources expense to membership services, transaction services, connectivity services, and port services. Thus, again, the Exchange's allocations of cost across core services were based on real costs of operating the Exchange and were not double-counted across the core services or their associated revenue streams.

As another example, the Exchange allocated depreciation expense to all core services, including market data, but in different amounts. The Exchange believes it is reasonable to allocate the identified portion of such expense because such expense includes the actual cost of the computer equipment, such as dedicated servers, computers, laptops, monitors, information security appliances and storage, and network switching infrastructure equipment, including switches and taps that were purchased to operate and support the network. Without this equipment, the Exchange would not be able to operate the network and provide the market data feeds to its Equity Members and their customers. However, the Exchange did not allocate all of the depreciation and amortization expense toward the cost of providing the market data feeds, but instead allocated approximately 0.5% of the Exchange's overall depreciation and amortization expense to the market data feeds combined. The Exchange allocated the remaining depreciation and amortization expense (99.5%) toward the cost of providing transaction services, membership services, connectivity services, and port services.

The Exchange notes that its revenue estimates are based on projections across all potential revenue streams and will only be realized to the extent such revenue streams actually produce the revenue estimated. The Exchange does not yet know whether such expectations will be realized. For instance, in order to generate the revenue expected from the market data feeds, the Exchange will have to be successful in retaining existing clients that wish to maintain subscriptions to those market data feeds or in obtaining new clients that will purchase such services. Similarly, the Exchange will have to be successful in retaining a positive net capture on transaction fees in order to realize the anticipated revenue from transaction pricing.

The Exchange notes that the Cost Analysis is based on the Exchange's 2024 fiscal year of operations and projections. It is possible, however, that actual costs may be higher or lower. To the extent the Exchange sees growth in use of market data services it will receive additional revenue to offset future cost increases. However, if use of market data services is static or decreases, the Exchange might not realize the revenue that it anticipates or needs in order to cover applicable costs. Accordingly, the Exchange is committing to conduct a one-year review after implementation of these fees. The Exchange expects that it may propose to adjust fees at that time, to increase fees in the event that revenues fail to cover costs and a reasonable mark-up of such costs. Similarly, the Exchange may propose to decrease fees in the event that revenue materially exceeds our current projections. In addition, the Exchange will periodically conduct a review to inform its decision making on whether a fee change is appropriate (*e.g.,* to monitor for costs increasing/decreasing or Distributors or Users increasing/decreasing, etc. in ways that suggest the then-current fees are becoming dislocated from the prior cost-based analysis) and would propose to increase fees in the event that revenues fail to cover its costs and a reasonable mark-up, or decrease fees in the event that revenue or the mark-up materially exceeds our current projections. In the event that the Exchange determines to propose a fee change, the results of a timely review, including an updated cost estimate, will be included in the rule filing proposing the fee change. More generally, the Exchange believes that it is appropriate for an exchange to refresh and update information about its relevant costs and revenues in seeking any future changes to fees, and the Exchange commits to do so.

Projected Revenue [35]

The proposed fees will allow the Exchange to cover certain costs incurred by the Exchange associated with creating, generating, and disseminating the market data feeds and the fact that the Exchange will need to fund future expenditures (increased costs, improvements, etc.). The Exchange routinely works to improve the performance of the network's hardware and software. The costs associated with maintaining and enhancing a state-of-the-art exchange network is a significant expense for the Exchange, and thus the Exchange believes that it is reasonable and appropriate to help offset those costs by amending fees for market data Distributors and Users. Distributors, particularly those of the market data feeds, expect the Exchange to provide this level of support so they continue to receive the performance they expect. This differentiates the Exchange from its competitors. As detailed above, the Exchange has five primary sources of revenue that it can potentially use to fund its operations: transaction fees, fees for connectivity services, membership and regulatory fees, and market data fees. Accordingly, the Exchange must cover its expenses from these five primary sources of revenue.

The Exchange's Cost Analysis estimates the annual cost to provide the market data feeds will equal $1,800,360. Based on the projected number of Distributors and Users, the Exchange would generate annual revenue of approximately $1,962,000 for the market data feeds. The Exchange believes this represents a modest profit of 8.2% when compared to the cost of providing the market data feeds, which the Exchange believes is fair and reasonable after taking into account the costs related to creating, generating, and disseminating the market data feeds and the fact that the Exchange will need to fund future expenditures (increased costs, improvements, etc.). To determine the

[35] To estimate the potential number of Distributors and their anticipated use after the proposed fees are implemented, the Exchange surveyed and reviewed its current Distributor base, considered the number of current potential Distributors who may unsubscribe due to the proposed fees being implemented, and sought informal feedback from Equity Members and other Distributors.

projected number of Distributors and Users, the Exchange reviewed its Distributor population from February 2024, the month preceding when the Exchange filed its proposal to implement fees for the market data products, and assumed a 5% attrition rate. The 5% attrition rate was based on surveying the current Distributor population when socializing the proposed fee structure with market participants. The Exchange also reviewed Distributor disclosures submitted to the Exchange to see how Distributors were using the market data, *e.g.,* for a Trading Platform, internal distribution, firm size, etc., and to which fee(s) they may be subject to under the proposed structure.

Based on the above discussion, the Exchange believes that even if the Exchange earns the above revenue or incrementally more or less, the proposed fees are fair and reasonable because they will not result in pricing that deviates from that of other exchanges or a supra-competitive profit, when comparing the total expense of the Exchange associated with providing the market data feeds versus the total projected revenue also associated with those market data feeds.

The Exchange did not charge any fees for the market data feeds since its inception in September 2020 and its allocation of costs to the market data feeds was part of a holistic allocation that also allocated costs to other core services without double-counting any expenses. The Exchange is owned by a holding company that is the parent company of four exchange markets and, therefore, the Exchange and its affiliated markets must allocate shared costs across all of those markets accordingly, pursuant to the above-described allocation methodology. In contrast, IEX and MEMX, which are currently each operating only one SRO, in their recent non-transaction fee filings allocate the entire amount of that same cost to a single SRO. This can result in lower profit margins for the non-transaction fees proposed by IEX and MEMX because the single allocated cost does not experience the efficiencies and synergies that result from sharing costs across multiple platforms.[36] The Exchange and its affiliated markets often share a single cost, which results in cost efficiencies that can cause a broader gap between the allocated cost amount and projected revenue, even though the fee levels being proposed are lower or competitive with competing markets (as described above). To the extent that the application of a cost-based standard results in Commission Staff making determinations as to the appropriateness of certain profit margins, the Commission Staff should consider whether the proposed fee level is comparable to, or competitive with, the same fee charged by competing exchanges and how different cost allocation methodologies (such as across multiple markets) may result in different profit margins for comparable fee levels. If Commission Staff is making determinations as to appropriate profit margins, the Exchange believes that the Commission should be clear to all market participants as to what they have determined is an appropriate profit margin and should apply such determinations consistently and, in the case of certain legacy exchanges, retroactively, if such standards are to avoid having a discriminatory effect. Further, the proposal reflects the Exchange's efforts to control its costs, which the Exchange does on an ongoing basis as a matter of good business practice. A potential profit margin should not be judged alone based on its size, but is also indicative of costs management and whether the ultimate fee reflects the value of the services provided. For example, a profit margin on one exchange should not be deemed excessive where that exchange has been successful in controlling its costs, but not excessive where on another exchange where that exchange is charging comparable fees but has a lower profit margin due to higher costs. Doing so could have the perverse effect of not incentivizing cost control where higher costs alone are used to justify fees increases.

Accordingly, while the Exchange is supportive of transparency around costs and potential margins (applied across all exchanges), as well as periodic review of revenues and applicable costs (as discussed below), the Exchange does not believe that these estimates should form the sole basis of whether or not a proposed fee is reasonable or can be adopted. Instead, the Exchange believes that the information should be used solely to confirm that an Exchange is not earning—or seeking to earn—supra-competitive profits, the standard set forth in the Staff Guidance. The Exchange believes the Cost Analysis and related projections in this filing demonstrate this fact.

The Proposed Fees Are Reasonable and Comparable to the Fees Charged By Other Exchanges for Similar Data Products

Overall. Among other things, the Exchange relying upon a cost-plus model to determine a reasonable fee structure that is informed by the Exchange's understanding of different uses of the products by different types of participants. In this context, the Exchange believes the proposed fees overall are fair and reasonable as a form of cost recovery plus the possibility of a reasonable return for the Exchange's aggregate costs of offering the market data feeds. The Exchange believes the proposed fees are reasonable because they are designed to generate annual revenue to recoup some or all of Exchange's annual costs of providing the market data feeds with a reasonable mark-up. As discussed above, the Exchange estimates this fee filing will result in annual revenue of approximately $1,980,000, representing a potential mark-up of just 9.1% over the cost of providing market data feeds. Accordingly, the Exchange believes that this fee methodology is reasonable because it allows the Exchange to recoup all of its expenses for providing the market data feeds (with any additional revenue representing no more than what the Exchange believes to be a reasonable rate of return). The Exchange also believes that the proposed fees are reasonable because they are generally similar to or less than the fees charged by competing equities exchanges for comparable market data products, notwithstanding that the competing exchanges may have different system architectures that may result in different cost structures for the provision of market data.

The Exchange also believes the proposed fees are reasonable when compared to fees charged for comparable products by other exchanges, including comparable data feeds priced significantly higher than the Exchange's proposed fees. Overall, the Exchange's proposed fees are generally lower or similar to fees charged by other exchanges.[37] For this

[36] The Exchange acknowledges that IEX included in its proposal to adopt market data fees after offering market data for free an analysis of what its projected revenue would be if all of its existing customers continued to subscribe versus what its projected revenue would be if a limited number of customers subscribed due to the new fees. *See* Securities Exchange Act Release No. 94630 (April 7, 2022), 87 FR 21945 (April 13, 2022) (SR–IEX–2022–02). MEMX did not include a similar analysis in its recent filing to adopt market data fees. *See* Securities Exchange Act Release No. 97130 (March 13, 2023), 88 FR 16491 (March 17, 2023) (SR–MEMX–2023–04).

[37] *See* MEMX Fee Schedule, *available at, https://info.memxtrading.com/membership-fees/* (''MEMX Fee Schedule''); Cboe BYX Fee Schedule, *available at, https://www.cboe.com/us/equities/membership/fee_schedule/byx/;* Cboe BZX Fee Schedule, *available at, https://www.cboe.com/us/equities/membership/fee_schedule/bzx/;* Cboe EDGA Fee Schedule, *available at, https://www.cboe.com/us/*

reason, the Exchange believes that the proposed fees are consistent with the Act generally, and Section 6(b)(5) [38] of the Act in particular. The Exchange believes that denying it the ability to adopt the proposed fees that would allow the Exchange to recoup its costs with a reasonable margin in a manner that is closer to parity with other exchanges, in effect, impedes its ability to compete, including in its pricing of transaction fees and ability to invest in competitive infrastructure and other offerings.

Internal Distribution Fees. The Exchange believes that it is reasonable to charge fees to access the market data feeds for Internal Distribution because of the value of such data to Distributors in their profit-generating activities. The Exchange also believes that the proposed monthly Internal Distribution fees are reasonable because they are similar to the amount charged by other exchanges for comparable data products. Specifically, the Exchange proposes to charge a monthly fee of $1,000.00 to Internal Distributors for the ToM feed and $2,000.00 for the DoM feed, both of which include last sale information. MEMX, Cboe BZX, and Cboe EDGX each charge Internal Distributors a monthly fee of $750.00 per month for their top-of-book products and $1,500.00 for their depth-of-book products, and charges separately for last sale information.[39] The Exchange notes that while its proposed fee for Internal Distributors may be slightly higher than these other exchanges, its other proposed fees are either equal to or significantly lower than other exchanges, as discussed below.

External Distribution Fees. The Exchange believes that it is reasonable to charge External Distribution fees for the market data feeds because vendors receive value from redistributing the data in their business products provided to their customers. The Exchange believes that charging External Distribution fees is reasonable because the vendors that would be charged such fees profit by re-transmitting the Exchange's market data to their customers. These fees would be charged only once per month to each vendor account that redistributes any of the market data feeds, regardless of the number of customers to which that vendor redistributes the data.

The Exchange also believes that the proposed monthly External Distribution fees are reasonable because they are equal to or lower than the amount charged by other exchanges for comparable data products. Specifically, the Exchange proposes to charge a monthly fee of $2,000.00 to External Distributor for the ToM feed and $2,500.00 for the DoM feed. The Exchange's proposed External Distribution fee for ToM is equal to or lower than the fees charged by MEMX, Cboe BZX, and Cboe EDGX to External Distributors of their depth-of-book products, who each charge $2,000.00, $2,500.00, and $2,250.00, respectively.[40] Meanwhile, the Exchange's proposed External Distribution fee for DoM is equal to the fees charged by MEMX, Cboe BYX, Cboe EDGA, and Cboe EDGX to External Distributors of their depth-of-book products.[41] Meanwhile, the Exchange's proposed External Distribution fee for DoM is lower than the $5,000.00 fee charged by Cboe BZX to External Distributors of its depth-of-book product.[42]

User Fees. The Exchange believes that having separate Professional and Non-Professional User fees for the market data feeds is reasonable because it will make the product more affordable and result in greater availability to Professional and Non-Professional Users. Setting a modest Non-Professional User fee is reasonable because it provides an additional method for Non-Professional Users to access the market data feeds by providing the same data that is available to Professional Users. The proposed monthly Professional User and Non-Professional User fees are reasonable because they equal to or are lower than the fees charged by other exchanges for comparable data products. For example, the Exchange's proposed Professional User fees of $2.00 for ToM and $30.00 for DoM is lower than the same fee charged by Cboe BZX and Cboe EDGX, who each charge $4.00 for their top-of-book products and $40.00 for their depth-of-book products.[43] The Exchange's proposed Non-Professional User fees of $0.10 for ToM is equal to the same fee charged by Cboe BZX and Cboe EDGX.[44]

Meanwhile, the Exchange's proposed Non-Professional User fees of $3.00 for DoM is equal to the same fee charged by MEMX and lower than the same fee charged by Cboe BZX and Cboe EDGX, who each charge $5.00 for their depth-of-book products.[45]

The Exchange also believes that the proposal to require reporting of individual Users, but not devices, is reasonable as this too will eliminate unnecessary audit risk that can arise when recipients are required to apply complex counting rules such as whether or not to count devices or whether an individual accessing the same data through multiple devices should be counted once or multiple times.

The Exchange also believes it is reasonable to adopt an Enterprise Fee because this would allow a market participant to disseminate such data feeds to an unlimited number of Users without the necessity of counting such Users. As this is an optional subscription, a data recipient is able to determine whether it prefers to count Users and report such Users to the Exchange or not, and also whether it is more economically advantageous to count and pay for specific Users or to subscribe to the Enterprise Fee. The Exchange also notes that only a market participant with a substantial number of Users would likely choose to subscribe for and pay the Enterprise Fee.

The proposed monthly Enterprise fees are reasonable because they equal to or are lower than the fees charged by other exchanges for comparable data products. For example, the Exchange's proposed Enterprise fee of $15,000.00 per month for ToM equals the same fee charged by Cboe BZX and Cboe EDGX.[46] However, the Exchange's proposed Enterprise fee of $25,000.00 per month for DoM is much lower than the same fee charged by Cboe BZX and Cboe EDGX, who each charge $100,000.00 per month.[47]

Non-Display Use Fees. The Exchange believes the proposed Non-Display Usage fees are reasonable because they reflect the value of the data to the data recipients in their profit-generating activities and do not impose the burden of counting non-display devices.

The Exchange believes that the proposed Non-Display Usage fees reflect the significant value of the non-display data use to data recipients, whom purchase such data on a voluntary basis. Non-display data can be used by data recipients for a wide variety of profit-generating purposes, including

equities/membership/fee_schedule/edga/; and Cboe EDGX Fee Schedule, *available at, https://www.cboe.com/us/equities/membership/fee_schedule/edgx/.*

[38] 15 U.S.C. 78f(b)(5).

[39] *See* MEMX Fee Schedule, *supra* note 37.

[40] *See* MEMX Fee Schedule, Cboe BZX Fee Schedule, *and* Cboe EDGX Fee Schedule, *supra* note 43.

[41] *See* MEMX Fee Schedule, Cboe BYX Fee Schedule, Cboe EDGA Fee Schedule, *and* Cboe EDGX Fee Schedule, *id.*

[42] *See* Cboe BZX Fee Schedule, *id.*

[43] *See* Cboe BZX Fee Schedule *and* Cboe EDGX Fee Schedule, *id.*

[44] *Id.*

[45] *See* MEMX Fee Schedule, Cboe BZX Fee Schedule, *and* Cboe EDGX Fee Schedule, *supra* note 43.

[46] *See* Cboe BZX Fee Schedule *and* Cboe EDGX Fee Schedule, *id.*

[47] *Id.*

proprietary and agency trading and smart order routing, as well as by data recipients that operate Trading Platforms that compete directly with the Exchange for order flow. The data also can be used for a variety of non-trading purposes that indirectly support trading, such as risk management and compliance. Although some of these non-trading uses do not directly generate revenues, they can nonetheless substantially reduce a recipient's costs by automating such functions so that they can be carried out in a more efficient and accurate manner and reduce

s and labor costs, thereby benefiting recipients. The Exchange believes that charging for non-trading uses is reasonable because data recipients can derive substantial value from such uses, for example, by automating tasks so that can be performed more quickly and accurately and less expensively than if they were performed manually.

Previously, the non-display use data pricing policies of many exchanges required customers to count, and the exchanges to audit the count of, the number of non-display devices used by a customer. As non-display use grew more prevalent and varied, however, exchanges received an increasing number of complaints about the impracticality and administrative burden associated with that approach. In response, several exchanges developed a non-display use pricing structure that does not require non-display devices to be counted or those counts to be audited, and instead categorizes different types of use. The Exchange proposes to distinguish between non-display use for the operation of a Trading Platform and other non-display use, which is similar to exchanges such as MEMX, BZX, and EDGX,[48] while other exchanges maintain additional categories and in many cases charge multiple times for different types of non-display use or the operation of multiple Trading Platforms.[49]

The Exchange believes that it is reasonable to segment the fee for non-display use into these two categories. As noted above, the uses to which customers can put the market data feeds are numerous and varied, and the Exchange believes that charging separate fees for these separate categories of use is reasonable because it reflects the actual value the customer derives from the data, based upon how the customer makes use of the data.

The Exchange believes that the proposed fees for Non-Display Usage for ToM are reasonable because the Exchange's proposed fee of $1,000.00 per month is less than the amounts charged by several other exchanges for comparable data products.[50] The Exchange also believes that the proposed fees for Non-Display Usage for DoM are reasonable because the Exchange's proposed fee of $2,500.00 per month for DoM equals the same fee charged by MEMX for its depth-of-book product.[51] The proposed fees are also significantly less than the amounts charged by several other exchanges for comparable data products.[52] In fact, the Exchange's proposed fees for Non-Display Usage fee may be even lower because the Exchange would allow Distributors to the DoM feed to also receive the ToM feed for no additional charge. The Exchange believes that the proposed fees directly and appropriately reflect the significant value of using data on a non-display basis in a wide range of computer-automated functions relating to both trading and non-trading activities and that the number and range of these functions continue to grow through innovation and technology developments. Further, the Exchange benefits from other non-display use by market participants (including the fact that the Exchange receives orders resulting from algorithms and routers) and both the Exchange and other participants benefit from other non-display use by market participants when such use is to support more broadly beneficial functions such as risk management and compliance.

The Exchange believes that the proposed fees for Non-Display Usage for ToM are reasonable because the Exchange's proposed fee of $2,500.00 per month is less than the amounts charged by several other exchanges for comparable data products,[53] which also charge per Trading Platform operated by a data Distributor subject to a cap in most cases, rather than charging per Distributor, as proposed by the Exchange.[54] The Exchange also believes that it is reasonable to charge the proposed fees for non-display use for operation of a Trading Platform of the DoM feed because its proposed fee of $2,500.00 per month equals the same fee charged by MEMX for its depth-of-book product.[55] The proposed fees are also significantly less than the amounts charged by Cboe BZX and Cboe EDGA, who each charge $5,000.00 per month, for comparable data products.[56] In fact, the Exchange's proposed fees for Non-Display Usage fee for Trading Platform may be even lower because the Exchange would allow Distributors to the DoM feed to also receive the ToM feed for no additional charge. The proposed fee is also significantly less than the amounts charged by several other exchanges for comparable data products, which also charge per Trading Platform operated by a data Distributor subject to a cap in most cases, rather than charging per Distributor, as proposed by the Exchange.[57] With respect to alternative trading systems, or ATSs, such platforms can utilize the Exchange Data Feeds to form prices for trading on such platforms but are not required to do so and can instead utilize SIP data. Currently, no ATS approved to trade NMS stocks subscribes to the Exchange's market data feeds.[58] With respect to other exchanges, which may choose to use the market data feeds for Regulation NMS compliance and order routing, the Exchange notes that several exchange competitors of the Exchange have not subscribed to any of the market data feeds and instead utilize SIP data for such purposes.[59] Accordingly, both ATSs and other exchanges clearly have a choice whether to subscribe to the Exchange's market data feeds.

The proposed Non-Display Usage fees are also reasonable because they take into account the extra value of receiving the data for Non-Display Usage that includes a rich set of information including top of book quotations, depth-of-book quotations, executions and other information. The Exchange believes that the proposed fees directly and appropriately reflect the significant value of using the market data feeds on

[48] *See* Cboe BZX Fee Schedule *and* Cboe EDGX Fee Schedule, *id.*

[49] *See* NYSE Proprietary Market Data Pricing Guide, dated May 4, 2022, *available at https://www.nyse.com/publicdocs/nyse/data/NYSE_Market_Data_Pricing.pdf, and* the Nasdaq Global Data Products pricing list, *available at https://nasdaqtrader.com/Trader.aspx?id=DPUSdata.*

[50] *Id.*

[51] *See* MEMX Fee Schedule, *supra* note 37.

[52] *See supra* note 49.

[53] *Id.*

[54] *See supra* note 49. The Exchange notes that MEMX also charges per Distributor, as proposed herein. *See* MEMX Fee Schedule *supra* note 37.

[55] *Id.*

[56] *See* Cboe BZX Fee Schedule *and* Cboe EDGX Fee Schedule, *supra* note 37. *See also supra* note 49.

[57] *See supra* note 49. The Exchange notes that MEMX also charges per Distributor, as proposed herein. *See* MEMX Fee Schedule *supra* note 37.

[58] MIAX Pearl Equities internal data regarding non-display use by Trading Platforms. As of March 15, 2024, there were currently 32 ATSs that had filed an effective Form ATS–N with the Commission to trade NMS stocks. *See https://www.sec.gov/divisions/marketreg/form-ats-n-filings.htm#ats-n.*

[59] *See, e.g.,* BZX Rule 11.26, EDGA Rule 13.4, EDGX Rule 13.4, and Long Term Stock Exchange, Inc. Rule 11.4010(a), each of which discloses the data feeds used by each respective exchange and state that SIP products are used with respect to MIAX Pearl Equities.

a non-display basis in a wide range of computer-automated functions relating to both trading and non-trading activities and that the number and range of these functions continue to grow through innovation and technology developments.[60]

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For all of the foregoing reasons, the Exchange believes that the proposed fees for the market data feeds are reasonable.

Equitable Allocation

Overall. The Exchange believes that its proposed fees are reasonable, fair, and equitable, and not unfairly discriminatory because they are designed to align fees with services provided. The Exchange believes the proposed fees for the market data feeds are allocated fairly and equitably among the various categories of users of the feeds, and any differences among categories of users are justified and appropriate.

The Exchange believes that the proposed fees are equitably allocated because they will apply uniformly to all data recipients that choose to subscribe to the market data feeds. Any market participant that chooses to subscribe to the market data feeds is subject to the same Fee Schedule, regardless of what type of business they operate, and the decision to subscribe to one or more market data feeds is based on objective differences in usage of market data feeds among different Equity Members, which are still ultimately in the control of any particular Equity Member. The Exchange believes the proposed pricing of the market data feeds is equitably allocated because it is based, in part, upon the amount of information contained in each data feed and the value of that information to market participants.

Internal Distributor Fees. The Exchange believes the proposed monthly fees for Internal Distributors of the market data feeds are equitably allocated because they would be charged on an equal basis to all data recipients that receive the market data feeds for internal distribution, regardless of what type of business they operate.

External Distributor Fees. The Exchange believes the proposed monthly fees for External Distributors of the market data feeds are equitably allocated and not unfairly discriminatory because they would be charged on an equal basis to all data recipients that receive the market data feeds that choose to redistribute the feeds externally, regardless of what business they operate. The Exchange also believes that the proposed monthly fees for External Distributors are equitably allocated when compared to lower proposed fees for Internal Distributors because data recipients that are externally distributing market data feeds are able to monetize such distribution and spread such costs amongst multiple third party data recipients, whereas the Internal Distributor fee is applicable to use by a single data recipient (and its affiliates).

The Exchange believes that it is reasonable and equitable discriminatory to assess Internal Distributors fees that are less than the fees assessed for External Distributors for subscriptions to the market data feeds because Internal Distributors have limited, restricted usage rights to the market data, as compared to External Distributors, which have more expansive usage rights. All Equity Members and non-Equity Members that decide to receive any market data feed of the Exchange must first execute, among other things, the MIAX Exchange Group Exchange Data Agreement (the ''Exchange Data Agreement'').[61] Pursuant to the Exchange Data Agreement, Internal Distributors are restricted to the ''internal use'' of any market data they receive. This means that Internal Distributors may only distribute the Exchange's market data to the recipient's officers and employees and its affiliates.[62] External Distributors may distribute the Exchange's market data to persons who are not officers, employees or affiliates of the External Distributor,[63] and may charge their own fees for the redistribution of such market data. External Distributors may monetize their receipt of the market data feeds by charging their customers fees for receipt of the Exchange's market data feeds. Internal Distributors do not have the same ability to monetize the Exchange's market data feeds. Accordingly, the Exchange believes it is fair, reasonable and not unfairly discriminatory to assess External Distributors a higher fee for the Exchange's market data feeds as External Distributors have greater usage rights to commercialize such market data and can adjust their own fee structures if necessary.

The Exchange also utilizes more resources to support External Distributors versus Internal Distributors, as External Distributors have reporting and monitoring obligations that Internal Distributors do not have, thus requiring additional time and effort of Exchange staff. For example, External Distributors have monthly reporting requirements under the Exchange's Market Data Policies.[64] Exchange staff must then, in turn, process and review information reported by External Distributors to ensure the External Distributors are redistributing the market data feeds in compliance with the Exchange's Market Data Agreement and Policies.

The Exchange believes the proposed fees are equitable because the fee level results in a reasonable and equitable allocation of fees amongst Distributors for similar services, depending on whether the Distributor is an Internal or External Distributor. Moreover, the decision as to whether or not to purchase market data is entirely optional to all market participants. Potential purchasers are not required to purchase the market data, and the Exchange is not required to make the market data available. Purchasers may request the data at any time or may decline to purchase such data. The allocation of fees among users is fair and reasonable because, if market participants decide not to subscribe to the data feed, firms can discontinue their use of the market data feeds.

User Fees. The Exchange believes that the fee structure differentiating Professional User fees from Non-Professional User fees for display use is equitable. This structure has long been used by other exchanges and the SIPs to reduce the price of data to Non-Professional Users and make it more broadly available.[65] Offering the market data feeds to Non-Professional Users at a lower cost than Professional Users results in greater equity among data recipients, as Professional Users are

[60] *See also* Exchange Act Release No. 69157 (March 18, 2013), 78 FR 17946, 17949 (March 25, 2013) (SR–CTA/CQ–2013–01) (''[D]ata feeds have become more valuable, as recipients now use them to perform a far larger array of non-display functions. Some firms even base their business models on the incorporation of data feeds into black boxes and application programming interfaces that apply trading algorithms to the data, but that do not require widespread data access by the firm's employees. As a result, these firms pay little for data usage beyond access fees, yet their data access and usage is critical to their businesses.'').

[61] *See* Exchange Data Agreement, *available at https://www.miaxglobal.com/markets/us-equities/pearl-equities/market-data-vendor-agreements.*

[62] *See id.*

[63] *See id.*

[64] *See* Section 6 of the Exchange's Market Data Agreement, *supra* note 61.

[65] *See, e.g.,* Securities Exchange Act Release No. 59544 (March 9, 2009), 74 FR 11162 (March 16, 2009) (SR–NYSE–2008–131) (establishing the $15 Non-Professional User Fee (Per User) for NYSE OpenBook); Securities Exchange Act Release No. 20002, File No. S7–433 (July 22, 1983), 48 FR 34552 (July 29, 1983) (establishing Non-Professional fees for CTA data); NASDAQ BX Equity 7 Pricing Schedule, Section 123.

categorized as such based on their employment and participation in financial markets, and thus, are compensated to participate in the markets. While Non-Professional Users too can receive significant financial benefits through their participation in the markets, the Exchange believes it is reasonable to charge more to those Users who are more directly engaged in the markets.

The Exchange believes it is equitable to adopt User fees for the DoM feed that are higher than the User fees for the ToM feed because, as described above, DoM contains significantly more data than the ToM feed. The Exchange believes it is equitable to have pricing based, in part, upon the amount of information contained in each data feed and the value of that information to market participants.

The Exchange also believes it is equitable to adopt an Enterprise Fee because this would allow a Distributors to disseminate such data feeds to an unlimited number of Users without the necessity of counting such Users. As this is an optional subscription, a data recipient is able to determine whether it prefers to count Users and report such Users to the Exchange or not, and also whether it is more economically advantageous to count and pay for specific Users or to subscribe to the Enterprise Fee.

Non-Display Usage Fees. The Exchange believes the proposed Non-Display Usage fees are equitably allocated because they would require Distributors to pay fees only for the uses they actually make of the data. As noted above, non-display data can be used by data recipients for a wide variety of profit-generating purposes (including trading and order routing) as well as purposes that do not directly generate revenues (such as risk management and compliance) but nonetheless substantially reduce the recipient's costs by automating certain functions. The Exchange believes that it is equitable to charge non-display data Distributors that use the market data feeds for purposes other than operation of a Trading Platform as proposed because all such Distributors would have the ability to use such data for as many non-display uses as they wish for one low fee. As noted above, this structure is comparable to that in place for the BZX Depth feed but several other exchanges charge multiple non-display fees to the same client to the extent they use a data feed in several different trading platforms or for several types of non-display use.[66]

The Exchange further believes that the fees for non-display use for operation of a Trading Platform and for non-display use other than operation of a Trading Platform are equitable because the Exchange is imposing the same flat fee for each category of non-display use.

The Exchange believes that it is equitable to charge a single fee per Distributor rather than multiple fees for a Distributor that operates more than one Trading Platform because operators of Trading Platforms are many times viewed as a single competing venue or group, even if there are multiple liquidity pools operated by the same competitor.

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For all of the foregoing reasons, the Exchange believes that the proposed fees for the market data feeds are equitably allocated.

The Proposed Fees Are Not Unfairly Discriminatory

The Exchange believes the proposed fees are not unfairly discriminatory because any differences in the application of the fees are based on meaningful distinctions between customers, and those meaningful distinctions are not unfairly discriminatory between customers.

Overall. The Exchange believes that the proposed fees are not unfairly discriminatory because they would apply to all data recipients that choose to subscribe to the same market data feed(s). Any market participant, including market data vendors, that chooses to subscribe to the market data feeds is subject to the same Fee Schedule, regardless of what type of business they operate. Because the proposed fees for DoM are higher, market participants seeking lower cost options may instead choose to receive data from the SIPs or through the ToM feed for a lower cost. Alternatively, market participants can choose to pay for the DoM feed to receive data in a single feed with depth-of-book information if such information is valuable to such market participants. The Exchange notes that market participants can also choose to subscribe to a combination of data feeds for redundancy purposes or to use different feeds for different purposes. In sum, each market participant has the ability to choose the best business solution for itself. The Exchange does not believe it is unfairly discriminatory to base pricing upon the amount of information contained in each data feed and the value of that information to market participants. As described above, the ToM feed can be utilized to trade on the Exchange but contain less information than that is available on the DoM feed (*i.e.,* even for a Distributor who takes both feeds, such feeds do not contain depth-of-book information). Thus, the Exchange believes it is not unfairly discriminatory for the products to be priced as proposed, with ToM having the lowest price and DoM a higher price.

Internal Distributor Fees. The Exchange believes the proposed monthly fees for Internal Distributors are not unfairly discriminatory because they would be charged on an equal basis to all data recipients that receive the same market data feed(s) for internal distribution, regardless of what type of business they operate.

External Distributor Fees. The Exchange believes the proposed monthly fees for redistributing the market data feeds are not unfairly discriminatory because they would be charged on an equal basis to all data recipients that receive the same market data feed(s) that choose to redistribute the feed(s) externally. The Exchange also believes that having higher monthly fees for External Distributors than Internal Distributors is not unfairly discriminatory because data recipients that are externally distributing the market data feeds are able to monetize such distribution and spread such costs amongst multiple third party data recipients, whereas the Internal Distributor fee is applicable to use by a single data recipient (and its affiliates).

User Fees. The Exchange believes that the fee structure differentiating Professional User fees from Non-Professional User fees for display use is not unfairly discriminatory. This structure has long been used by other exchanges and the SIPs to reduce the price of data to Non-Professional Users and make it more broadly available.[67] Offering the market data feeds to Non-Professional Users with the same data as is available to Professional Users, albeit at a lower cost, results in greater equity among data recipients. These User fees would be charged uniformly to all individuals that have access to the market data feeds based on the category of User.

The Exchange also believes the proposed User fees for DoM are not unfairly

[66] *See supra* note 49.

[67] *See supra* note 65.

discriminatory, even though substantially higher than the proposed User fees for ToM because, as described above, DoM has significantly more information than ToM and is thus potentially more valuable to such Users.

The Exchange further believes that its proposal to adopt an Enterprise Fee is not unfairly discriminatory because this optional alternatives to counting and paying for specific Users will provide market participants the ability to provide information from the market data feeds to large numbers of Users without counting and paying for each individual User.

Non-Display Use Fees. The Exchange believes the proposed Non-Display Usage fees are not unfairly discriminatory because they would require Distributors for non-display use to pay fees depending on their use of the data, either for operation of a Trading Platform or not, but would not impose multiple fees to the extent a Distributor operates multiple Trading Platforms or has multiple different types of non-display use. As noted above, non-display data can be used by data recipients for a wide variety of profit-generating purposes as well as purposes that do not directly generate revenues but nonetheless substantially reduce the recipient's costs by automating certain functions. This segmented fee structure is not unfairly discriminatory because no Distributor of non-display data would be charged a fee for a category of use in which it did not actually engage.

The Exchange believes that it is not unreasonably discriminatory to charge a single fee for an operator of Trading Platforms that operates more than one Trading Platform because operators of Trading Platforms are many times viewed as a single competing venue or group, even if there a multiple liquidity pools operated by the same competitor. The Exchange again notes that certain competitors to the Exchange charge for non-display usage per Trading Platform,[68] in contrast to the Exchange's proposal. In turn, to the extent they subscribe to the market data feeds, these same competitors will benefit from the Exchange's pricing model to the extent they operate multiple Trading Platforms (as most do) by paying a single fee rather than paying for each Trading Platform that they operate that consumes the market data feeds.

* * * * *

For all of the foregoing reasons, the Exchange believes that the proposed fees for the Exchange's market data feeds are not unfairly discriminatory.

[68] *See supra* note 49.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[69] the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intra-Market Competition

The Exchange does not believe that the proposed fees place certain market participants at a relative disadvantage to other market participants because, as noted above, the proposed fees are associated with usage of the data feed by each market participant based on whether the market participant internally or externally distributes the Exchange data, which are still ultimately in the control of any particular Equity Member, and such fees do not impose a barrier to entry to smaller participants. Accordingly, the proposed fees do not favor certain categories of market participants in a manner that would impose a burden on competition; rather, the allocation of the proposed fees reflects the types of data consumed by various market participants and their usage thereof.

Inter-Market Competition

The Exchange does not believe the proposed fees place an undue burden on competition on other SROs that is not necessary or appropriate. In particular, market participants are not forced to subscribe to either data feed, as described above. Additionally, other exchanges have similar market data fees with comparable rates in place for their participants.[70] The proposed fees are based on actual costs and are designed to enable the Exchange to recoup its applicable costs with the possibility of a reasonable profit on its investment as described in the Purpose and Statutory Basis sections. Competing exchanges are free to adopt comparable fee structures subject to the Commission's rule filing process.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[71] and Rule 19b–4(f)(2)[72] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–PEARL–2024–22 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–PEARL–2024–22. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and

[69] 15 U.S.C. 78f(b)(8).

[70] *See supra* note 37.

[71] 15 U.S.C. 78s(b)(3)(A)(ii).

[72] 17 CFR 240.19b–4(f)(2).

copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–PEARL–2024–22 and should be submitted on or before June 7, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[73]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–10820 Filed 5–16–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100124; File No. SR–CboeEDGX–2024–024]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule

May 13, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 1, 2024, Cboe EDGX Exchange, Inc. (''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') proposes to amend its Fee Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/edgx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedule applicable to its equities trading platform (''EDGX Equities'') by: (1) modifying the Cross Asset Tier; (2) modifying Non-Displayed Add Volume Tier 1; and (3) modifying Retail Volume Tier 1. The Exchange proposes to implement these changes effective May 1, 2024.

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 16 registered equities exchanges, as well as a number of alternative trading systems and other off-exchange venues that do not have similar self-regulatory responsibilities under the Securities Exchange Act of 1934 (the ''Act''), to which market participants may direct their order flow. Based on publicly available information,[3] no single registered equities exchange has more than 16% of the market share. Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow. The Exchange in particular operates a ''Maker-Taker'' model whereby it pays rebates to members that add liquidity and assesses fees to those that remove liquidity. The Exchange's Fee Schedule sets forth the standard rebates and rates applied per share for orders that provide and remove liquidity, respectively. Currently, for orders in securities priced at or above $1.00, the Exchange provides a standard rebate of $0.00160 per share for orders that add liquidity and assesses a fee of $0.0030 per share for orders that remove liquidity.[4] For orders in securities priced below $1.00, the Exchange provides a standard rebate of $0.00003 per share for orders that add liquidity and assesses a fee of 0.30% of the total dollar value for orders that remove liquidity.[5] Additionally, in response to the competitive environment, the Exchange also offers tiered pricing which provides Members opportunities to qualify for higher rebates or reduced fees where certain volume criteria and thresholds are met. Tiered pricing provides an incremental incentive for Members to strive for higher tier levels, which provides increasingly higher benefits or discounts for satisfying increasingly more stringent criteria.

Cross Asset Tier

Under footnote 1 of the Fee Schedule, the Exchange currently offers various Add/Remove Volume Tiers that provide enhanced rebates for orders yielding fee codes B,[6] V,[7] Y,[8] 3,[9] and 4.[10] In particular, the Exchange offers a Cross Asset Tier that is designed to incentivize Members to achieve certain levels of participation on both the Exchange's equities and options platform (''EDGX Options''). Now, the Exchange proposes to modify the second prong of criteria associated with the Cross Asset Tier. The current criteria is as follows:

- The Cross Asset Tier provides a rebate of $0.0029 per share for securities priced above $1.00 for qualifying orders (*i.e.,* orders yielding fee codes B, V, Y, 3, or 4) where (1) Member has a Tape B & C ADAV[11] ≥ 6,000,000; and (2) Member has an Add ADV[12] on EDGX Options ≥ 300,000 in SPY.

The proposed criteria is as follows:

[73] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (April 26, 2024), available at *https://www.cboe.com/us/equities/market_statistics/.*

[4] *See* EDGX Equities Fee Schedule, Standard Rates.

[5] *Id.*

[6] Fee code B is appended to orders that add liquidity to EDGX in Tape B securities.

[7] Fee code V is appended to orders that add liquidity to EDGX in Tape A securities.

[8] Fee code Y is appended to orders that add liquidity to EDGX in Tape C securities.

[9] Fee code 3 is appended to orders that add liquidity to EDGX in Tape A or Tape C securities during the pre and post market.

[10] Fee code 4 is appended to orders that add liquidity to EDGX in Tape B securities during the pre and post market.

[11] ADAV means average daily added volume calculated as the number of shares added per day. ADAV is calculated on a monthly basis.

[12] ADV means average daily volume calculated as the number of shares added to, removed from, or routed by, the Exchange, or any combination or subset thereof, per day. ADV is calculated on a monthly basis.

• The Cross Asset Tier provides a rebate of $0.0029 per share for securities priced above $1.00 for qualifying orders (*i.e.,* orders yielding fee codes B, V, Y, 3, or 4) where (1) Member has a Tape B & C ADAV ≥ 6,000,000; and (2) Member has an Add ADV in SPY on EDGX Options ≥ 0.70% of average OCV.[13]

Non-Displayed Add Volume Tier

Also under footnote 1, the Exchange offers five Non-Displayed Add Volume Tiers that each provide an enhanced rebate for Members' qualifying orders yielding fee codes DM,[14] HA,[15] MM,[16] and RP,[17] where a Member reaches certain volume-based criteria offered in each tier. Now, the Exchange proposes to modify the criteria of Non-Displayed Add Volume Tier 1. The current criteria is as follows:

• Non-Displayed Add Volume Tier 1 provides a rebate of $0.0015 per share for securities priced at or above $1.00 for qualifying orders (*i.e.,* orders yielding fee codes DM, HA, MM, or RP) where a Member has an ADAV ≥ 0.05% of TCV [18] for Non-Displayed orders that yield fee codes DM, HA, HI,[19] HM, or RP.

The proposed criteria is as follows:

• Non-Displayed Add Volume Tier 1 provides a rebate of $0.0015 per share for securities priced at or above $1.00 for qualifying orders (*i.e.,* orders yielding fee codes DM, HA, MM, or RP) where a Member has an ADAV ≥ 0.07% of TCV for Non-Displayed orders that yield fee codes DM, HA, HI, HM, or RP.

Retail Volume Tier

Under footnote 2 of the Fee Schedule, the Exchange currently offers various Retail Volume Tiers which provide an enhanced rebate for Retail Member Organizations (''RMOs'') [20] an opportunity to receive an enhanced rebate from the standard rebate for Retail Orders [21] that add liquidity (*i.e.,* yielding fee code ZA or ZO). Currently, the Exchange offers three Retail Volume Tiers where an RMO is eligible for an enhanced rebate for qualifying orders (*i.e.,* yielding fee code ZA or ZO) meeting certain add volume-based criteria. The Exchange now proposes to modify the criteria of Retail Volume Tier 1. Currently, the criteria is as follows:

• Retail Volume Tier 1 provides a rebate of $0.0034 for securities priced at or above $1.00 for qualifying orders (*i.e.,* orders yielding fee codes ZA or ZO) where a Member adds a Retail Order ADV (*i.e.,* yielding fee codes ZA or ZO) ≥ 0.35% of the TCV.

The proposed criteria is as follows:

• Retail Volume Tier 1 provides a rebate of $0.0034 for securities priced at or above $1.00 for qualifying orders (*i.e.,* orders yielding fee codes ZA or ZO) where (1) Member adds a Retail Order ADV (*i.e.,* yielding fee codes ZA or ZO) ≥ 0.30% of the TCV; and (2) Member has an ADAV (*i.e.* yielding fee codes B, V, or Y) ≥ 20,000,000.

Together, the proposed modifications to the Cross Asset Tier, Non-Displayed Add Volume Tier 1 and Retail Volume Tier 1 are each intended to provide Members an opportunity to earn an enhanced rebate by increasing their order flow to the Exchange, which further contributes to a deeper, more liquid market and provides even more execution opportunities for active market participants. Incentivizing an increase in liquidity adding volume through enhanced rebate opportunities encourages liquidity adding Members on the Exchange to contribute to a deeper, more liquid market, providing for overall enhanced price discovery and price improvement opportunities on the Exchange. As such, increased overall order flow benefits all Members by contributing towards a robust and well-balanced market ecosystem.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[22] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [23] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [24] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers as well as Section 6(b)(4) [25] as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities.

As described above, the Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. The Exchange believes that its proposal to modify the Cross Asset Tier, Non-Displayed Add Volume Tier 1, and Retail Volume Tier 1 reflects a competitive pricing structure designed to incentivize market participants to direct their order flow to the Exchange, which the Exchange believes would enhance market quality to the benefit of all Members. Specifically, the Exchange's proposal to introduce slightly different criteria to the Cross Asset Tier, Non-Displayed Add Volume Tier 1, and Retail Volume Tier 1 is not a significant departure from existing criteria, is reasonably correlated to the enhanced rebate offered by the Exchange and other competing exchanges,[26] and will continue to

[13] OCV means, for purposes of equities pricing, the total equity and ETF options volume that clears in the Customer range at the Options Clearing Corporation (''OCC'') for the month for which the fees apply, excluding volume on any day that the Exchange experiences an Exchange System Disruption and on any day with a scheduled early market close, using the definition of Customer as provided under the Exchange's fee schedule for EDGX Options.

[14] Fee code DM is appended to orders that add liquidity using MidPoint Discretionary Order within discretionary range.

[15] Fee code HA is appended to non-displayed orders that add liquidity to EDGX.

[16] Fee code MM is appended to non-displayed orders that add liquidity to EDGX using Mid-Point Peg.

[17] Fee code RP is appended to non-displayed orders that add liquidity to EDGX using Supplemental Peg.

[18] TCV means total consolidated volume calculated as the volume reported by all exchanges and trade reporting facilities to a consolidated transaction reporting plan for the month for which the fees apply.

[19] Fee code HI is appended to non-displayed orders that receive price improvement and add liquidity to EDGX.

[20] *See* EDGX Rule 11.21(a)(1). A ''Retail Member Organization'' or ''RMO'' is a Member (or a division thereof) that has been approved by the Exchange under this Rule to submit Retail Orders.

[21] *See* EDGX Rule 11.21(a)(2). A ''Retail Order'' is an agency or riskless principal order that meets the criteria of FINRA Rule 5320.03 that originates from a natural person and is submitted to the Exchange by a Retail Member Organization, provided that no change is made to the terms of the order with respect to price or side of the market and the order does not originate from a trading algorithm or any other computerized methodology.

[22] 15 U.S.C. 78f(b).

[23] 15 U.S.C. 78f(b)(5).

[24] *Id.*

[25] 15 U.S.C. 78f(b)(4).

[26] *See* MIAX Pearl Equities Exchange Fee Schedule, Remove Volume Tiers, available at *https://www.miaxglobal.com/sites/default/files/fee_*

Continued

incentivize Members to submit order flow to the Exchange. Additionally, the Exchange notes that relative volume-based incentives and discounts have been widely adopted by exchanges,[27] including the Exchange,[28] and are reasonable, equitable and non-discriminatory because they are open to all Members on an equal basis and provide additional benefits or discounts that are reasonably related to (i) the value to an exchange's market quality and (ii) associated higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns. Competing equity exchanges offer similar tiered pricing structures, including schedules of rebates and fees that apply based upon members achieving certain volume and/or growth thresholds, as well as assess similar fees or rebates for similar types of orders, to that of the Exchange.

In particular, the Exchange believes its proposal to modify the Cross Asset Tier, Non-Displayed Add Volume Tier 1, and Retail Volume Tier 1 is reasonable because the revised tiers will be available to all Members and provide all Members with an opportunity to receive an enhanced rebate. The Exchange further believes its proposal to modify the Cross Asset Tier, Non-Displayed Add Volume Tier 1, and Retail Volume Tier 1 will provide a reasonable means to encourage liquidity adding displayed and non-displayed orders in Members' order flow to the Exchange and to incentivize Members to continue to provide liquidity adding and liquidity removing volume to the Exchange by offering them an opportunity to receive an enhanced rebate on qualifying orders. An overall increase in activity would deepen the Exchange's liquidity pool, offer additional cost savings, support the quality of price discovery, promote market transparency and improve market quality, for all investors.

The Exchange believes that its proposed modifications to the Cross Asset Tier, Non-Displayed Add Volume Tier 1, and Retail Volume Tier 1 are reasonable as they do not represent a significant departure from the criteria currently offered in the Fee Schedule. The Exchange also believes that the proposal represents an equitable allocation of fees and rebates and is not unfairly discriminatory because all Members will be eligible for the proposed new tiers and have the opportunity to meet the tiers' criteria and receive the corresponding enhanced rebate if such criteria is met. Without having a view of activity on other markets and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would definitely result in any Members qualifying the new proposed tiers. While the Exchange has no way of predicting with certainty how the proposed changes will impact Member activity, based on the prior months volume, the Exchange anticipates that at least one Member will be able to satisfy the proposed Cross Asset Tier, at least one Member will be able to satisfy proposed Non-Displayed Add Volume Tier 1, and at least one Member will be able to satisfy proposed Retail Volume Tier 1. The Exchange also notes that proposed changes will not adversely impact any Member's ability to qualify for enhanced rebates offered under other tiers. Should a Member not meet the proposed new criteria, the Member will merely not receive that corresponding enhanced rebate.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, as discussed above, the Exchange believes that the proposed changes would encourage the submission of additional order flow to a public exchange, thereby promoting market depth, execution incentives and enhanced execution opportunities, as well as price discovery and transparency for all Members. As a result, the Exchange believes that the proposed changes further the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.''

The Exchange believes the proposed rule changes do not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the proposed changes to the Cross Asset Tier, Non-Displayed Add Volume Tier 1, and Retail Volume Tier 1 will apply to all Members equally in that all Members are eligible for each of the Tiers, have a reasonable opportunity to meet the Tiers' criteria and will receive the enhanced rebate on their qualifying orders if such criteria is met. The Exchange does not believe the proposed changes burden competition, but rather, enhances competition as it is intended to increase the competitiveness of EDGX by amending existing pricing incentives and adopting pricing incentives in order to attract order flow and incentivize participants to increase their participation on the Exchange, providing for additional execution opportunities for market participants and improved price transparency. Greater overall order flow, trading opportunities, and pricing transparency benefits all market participants on the Exchange by enhancing market quality and continuing to encourage Members to send orders, thereby contributing towards a robust and well-balanced market ecosystem.

Next, the Exchange believes the proposed rule changes does not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As previously discussed, the Exchange operates in a highly competitive market. Members have numerous alternative venues that they may participate on and direct their order flow, including other equities exchanges, off-exchange venues, and alternative trading systems. Additionally, the Exchange represents a small percentage of the overall market. Based on publicly available information, no single equities exchange has more than 16% of the market share.[29] Therefore, no exchange possesses significant pricing power in the execution of order flow. Indeed, participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [30] The fact that this market is competitive has also long been recognized by the courts. In NetCoalition v. Securities and Exchange Commission, the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is

schedule-files/MIAX_Pearl_Equities_Fee_Schedule_04042024.pdf. See also MEMX Equities Fee Schedule, Liquidity Removal Tier, available at *https://info.memxtrading.com/equities-trading-resources/us-equities-fee-schedule/.*

[27] *See e.g.*, BZX Equities Fee Schedule, Footnote 1, Add/Remove Volume Tiers.

[28] *See e.g.*, EDGX Equities Fee Schedule, Footnote 1, Add/Remove Volume Tiers.

[29] *Supra* note 3.

[30] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers' . . .''.[31] Accordingly, the Exchange does not believe its proposed fee change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [32] and paragraph (f) of Rule 19b–4 [33] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeEDGX–2024–024 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–CboeEDGX–2024–024. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeEDGX–2024–024 and should be submitted on or before June 7, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–10819 Filed 5–16–24; 8:45 am]

BILLING CODE 8011–01–P

[31] NetCoalition v. SEC, 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[32] 15 U.S.C. 78s(b)(3)(A).

[33] 17 CFR 240.19b–4(f).

[34] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100117; File No. SR–NASDAQ–2024–020]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Fees for Connectivity and Co-Location Services

May 13, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 29, 2024, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's fees for connectivity and co-location services, as described further below.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's fees relating to connectivity and co-location services.[3] Specifically, the Exchange proposes to raise its fees for connectivity and co-location services in General 8, fees assessed for remote multi-cast ITCH (''MITCH'') Wave Ports in Equity 7, Section 115, and certain fees related to Nasdaq Testing Facilities in Equity 7, Section 130 by 5.5%, with certain exceptions.

General 8, Section 1 includes the Exchange's fees that relate to connectivity, including fees for cabinets, external telco/inter-cabinet connectivity fees, fees for connectivity to the Exchange, fees for connectivity to third party services, fees for market data connectivity, fees for cabinet power install, and fees for additional charges and services. General 8, Section 2 includes the Exchange's fees for direct connectivity services, including fees for direct circuit connection to the Exchange, fees for direct circuit connection to third party services, and fees for point of presence connectivity. With the exception of the Exchange's GPS Antenna fees and the Cabinet Proximity Option Fee for cabinets with power density >10kW,[4] the Exchange proposes to increase its fees throughout General 8 by 5.5%.

In addition to increasing fees in General 8, the Exchange also proposes to increase certain fees in Equity 7. First, the Exchange proposes to increase the installation and recurring monthly fees assessed for remote MITCH Wave Ports[5] in Equity 7, Section 115(g)(1) by 5.5%. In addition, the Exchange proposes to increase certain fees in Section 130(d), which relate to the Nasdaq Testing Facility. Equity 7, Section 130(d)(1)(C) provides that subscribers to the Nasdaq Testing Facility (''NTF'') located in Carteret, New Jersey shall pay a fee of $1,000 per hand-off, per month for connection to the NTF. The hand-off fee includes either a 1Gb or 10Gb switch port and a cross connect to the NTF. In addition, Equity 7, Section 130(d)(1)(C) provides that subscribers shall also pay a one-time installation fee of $1,000 per hand-off. The Exchange proposes to increase these aforementioned fees by 5.5% to require that subscribers to the NTF shall pay a fee of $1,055 per hand-off, per month for connection to the NTF and a one-time installation fee of $1,055 per hand-off.

The proposed increases in fees would enable the Exchange to maintain and improve its market technology and services. With the exception of fees that were established as part of a new service in 2017 (and have remained unchanged since their adoption), the Exchange has not increased any of the fees included in the proposal since 2015, and many of the fees date back to between 2010 and 2014. However, since 2015, there has been notable inflation. Between 2015 and 2024, the dollar had an average inflation rate of 2.97% per year, producing a cumulative price increase of 30.12%.[6] Notwithstanding inflation, the Exchange historically has not increased its fees every year.[7] The proposed fees represent a 5.5% increase from the current fees, which is far below inflation since 2015, which exceeded 30%.[8] In addition to being far below the cumulative inflation rate since 2015, the Exchange also believes that the proposed 5.5% increase is reasonable because it is comparable to recent inflation rates for one-year periods. For example, in 2023, the inflation rate was 4.12% and in 2022, the inflation rate was 8%.[9] The Exchange is sensitive to the sticker shock that would occur if the Exchange raised its fees by more than 30% and therefore proposes a more modest increase, similar to that of inflation in recent one-year periods.

The Exchange believes that it is reasonable to increase its fees to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2015. The Exchange notes that this inflationary effect is a general phenomenon that is independent of any change in the Exchange's costs in providing its goods and services. The Exchange believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects. The Exchange notes that other exchanges have filed for comparable or higher increases in certain connectivity-related fees, based in part on similar rationale.[10]

In addition, the Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding Nasdaq's existing co-location facility to offer customers additional space and power. These investments, and the value they provide to customers, far exceed the amount of the proposed price increases. It is reasonable and consistent with the Act for the Commission to allow the Exchange to recoup these investments by charging fees, lest the Commission will disincentivize the Exchange to make similar investments in the future—a result that would be detrimental to the Exchange's competitiveness as well as the interests of market participants and investors.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[11] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[12] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

This belief is based on a couple factors. First, the current fees do not properly reflect the value of the services and products, as fees for the services and products in question have been static in nominal terms, and therefore falling in real terms due to inflation. Second, exchange fees are constrained

[3] The Exchange initially filed the proposed pricing change on March 1, 2024 (SR–NASDAQ–2024–008). The instant filing replaces SR–NASDAQ–2024–008, which was withdrawn on April 29, 2024.

[4] The Exchange proposes to exclude the GPS Antenna fees from the proposed fee increase because, unlike the other fees in General 8, the Exchange recently increased its GPS Antenna fees. *See* Securities Exchange Act Release No. 34–99126 (December 8, 2023), 88 FR 86712 (December 14, 2023) (SR–NASDAQ–2023–052). The Exchange also proposes to exclude the Cabinet Proximity Option Fee for cabinets with power density >10kW from the proposed fee increase because the Exchange recently established such fee. *See* Securities Exchange Act Release No. 34–99796 (March 20, 2024), 89 FR 21088 (March 26, 2024) (SR–NASDAQ–2024–013).

[5] Remote MITCH Wave Ports are for clients co-located at other third-party data centers, through which NASDAQ TotalView ITCH market data is distributed after delivery to those data centers via wireless network.

[6] *See https://www.officialdata.org/us/inflation/2015?amount=1* (Last updated February 27, 2024).

[7] Unregulated competitors providing connectivity and co-location services often have annual price increases written into their agreements with customers to account for inflation and rising costs.

[8] Between 2017 and 2024, inflation exceeded 25%. *See https://www.officialdata.org/us/inflation/2017?amount=1* (Last updated February 27, 2024).

[9] *See https://www.officialdata.org/us/inflation/2022?endYear=2023&amount=1.*

[10] *See, e.g.,* Securities Exchange Act Release No. 34–100004 (April 22, 2024), 89 FR 32465 (April 26, 2024) (SR–CboeBYX–2024–012).

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(4) and (5).

by the fact that market participants can choose among 16 different venues for equities trading and 17 different venues for options trading, and therefore no single venue can charge excessive fees for its products without losing customers and market share.

Real Exchange Fees Have Fallen

As explained above, with the exception of fees that were established as part of a new service in 2017 (and have remained unchanged since their adoption), the Exchange has not increased any of the fees included in the proposal since 2015, and many of the fees date back to between 2010 and 2014. This means that such fees have fallen in real terms due to inflation, which has been notable. Between 2015 and 2024, the dollar had an average inflation rate of 2.97% per year, producing a cumulative price increase of 30.12%.[13] Notwithstanding inflation, the Exchange historically has not increased its fees every year.[14] As noted above, the Exchange has not increased the fees in this proposal for over 8 years (or in the case of services introduced in 2017, for over 6 years since the services were introduced). Accordingly, the Exchange believes that the proposed fees are reasonable as they represent a 5.5% increase from the current fees, which is far below inflation since 2015, which exceeded 30%.[15] In addition to being far below the inflation rate since 2015, the Exchange also believes that the proposed 5.5% increase is reasonable because it is comparable to recent inflation rates for one-year periods. For example, in 2023, the inflation rate was 4.12% and in 2022, the inflation rate was 8%.[16] The Exchange is sensitive to the sticker shock that would occur if the Exchange raised its fees by more than 30% and therefore proposes a more modest increase, similar to that of inflation in recent one-year periods.

The Exchange believes that it is reasonable to increase its fees to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2015. The Exchange notes that this inflationary effect is a general phenomenon that is independent of any change in the Exchange's costs in providing its goods and services. The Exchange believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects.

In addition, the Exchange continues to invest in maintaining, improving, and enhancing its connectivity and co-location products, services, and facilities—for the benefit and often at the behest of its customers. Such enhancements include refreshing hardware and expanding Nasdaq's existing co-location facility to offer customers additional space and power. Again, these investments, and the value they provide to customers, far exceed the amount of the proposed price increases. It is reasonable and consistent with the Act for the Commission to allow the Exchange to recoup these investments by charging fees, lest the Commission will disincentivize the Exchange to make similar investments in the future—a result that would be detrimental to the Exchange's competitiveness as well as the interests of market participants and investors.

Customers Have a Choice in Trading Venue

Customers face many choices in where to trade both equities and options. Market participants will continue to choose trading venues and the method of connectivity based on their specific needs. No broker-dealer is required to become a Member of the Exchange. There is no regulatory requirement that any market participant connect to any one exchange, nor that any market participant connect at a particular connection speed or act in a particular capacity on the Exchange, or trade any particular product offered on an exchange. Moreover, membership is not a requirement to participate on the Exchange. Indeed, the Exchange is unaware of any one exchange whose membership includes every registered broker-dealer. The Exchange also believes substitutable products and services are available to market participants, including, among other things, other equities and options exchanges that a market participant may connect to in lieu of the Exchange, indirect connectivity to the Exchange via a third-party reseller of connectivity, and/or trading of equities or options products within markets which do not require connectivity to the Exchange, such as the Over-the-Counter (OTC) markets.

There are currently 16 registered equities exchanges that trade equities and 17 exchanges offering options trading services. No single equities exchange has more than 15% of the market share.[17] No single options exchange trades more than 14% of the options market by volume and only one of the 17 options exchanges has a market share over 10 percent.[18] This broad dispersion of market share demonstrates that market participants can and do exercise choice in trading venues. Further, low barriers to entry mean that new exchanges may rapidly enter the market and offer additional substitute platforms to further compete with the Exchange and the products it offers.

As such, the Exchange must set its fees, including its fees for connectivity and co-location services and products, competitively. If not, customers may move to other venues or reduce use of the Exchange's services. ''If competitive forces are operative, the self-interest of the exchanges themselves will work powerfully to constrain unreasonable or unfair behavior.'' [19] Accordingly, ''the existence of significant competition provides a substantial basis for finding that the terms of an exchange's fee proposal are equitable, fair, reasonable, and not unreasonably or unfairly discriminatory.'' [20] Disincentivizing market participants from purchasing Exchange connectivity would only serve to discourage participation on the Exchange, which ultimately does not benefit the Exchange. Moreover, if the Exchange charges excessive fees, it may stand to lose not only connectivity revenues but also other revenues, including revenues associated with the execution of orders.

In summary, the proposal represents an equitable allocation of reasonable dues, fees and other charges because Exchange fees have fallen in real terms and customers have a choice in trading venue and will exercise that choice and trade at another venue if exchange fees are not set competitively.

No Unfair Discrimination

The Exchange believes that the proposed fee changes are not unfairly discriminatory because the fees are assessed uniformly across all market participants that voluntarily subscribe

[13] *See https://www.officialdata.org/us/inflation/2015?amount=1* (Last updated February 27, 2024).

[14] As noted above, unregulated competitors providing connectivity and co-location services often have annual price increases written into their agreements with customers to account for inflation and rising costs.

[15] Between 2017 and 2024, inflation exceeded 25%. *See https://www.officialdata.org/us/inflation/2017?amount=1* (Last updated February 27, 2024).

[16] *See https://www.officialdata.org/us/inflation/2022?endYear=2023&amount=1.*

[17] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (Last updated January 11, 2024), available at *https://www.cboe.com/us/equities/market_statistics/.*

[18] *See* Nasdaq, Options Market Statistics (Last updated January 11, 2024), available at *https://www.nasdaqtrader.com/Trader.aspx?id=OptionsVolumeSummary.*

[19] *See* Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74,770 (December 9, 2008) (SR–NYSEArca–2006–21).

[20] *Id.*

to or purchase connectivity and co-location services or products, which are available to all customers.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Nothing in the proposal burdens inter-market competition (the competition among self-regulatory organizations) because approval of the proposal does not impose any burden on the ability of other exchanges to compete. The Exchange operates in a highly competitive market in which market participants can determine whether or not to connect to the Exchange based on the value received compared to the cost of doing so. Indeed, market participants have numerous alternative exchanges that they may participate on and direct their order flow, as well as off-exchange venues, where competitive products are available for trading.

Nothing in the proposal burdens intra-market competition (the competition among consumers) because the Exchange's connectivity and co-location services are available to any customer under the same fee schedule as any other customer, and any market participant that wishes to purchase such services can do so on a non-discriminatory basis.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[21]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

[21] 15 U.S.C. 78s(b)(3)(A)(ii).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NASDAQ–2024–020 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NASDAQ–2024–020. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NASDAQ–2024–020 and should be submitted on or before June 7, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–10826 Filed 5–16–24; 8:45 am]

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[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100113; File No. SR–CboeBYX–2024–004]

Self-Regulatory Organizations; Cboe BYX Exchange, Inc.; Order Instituting Proceedings To Determine Whether To Approve or Disapprove Proposed Rule Change To Amend the Definition of Retail Order, and Codify Interpretations and Policies Regarding Permissible Uses of Algorithms by RMOs

May 13, 2024.

I. Introduction

On January 25, 2024, Cboe BYX Exchange, Inc (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend the definition of Retail Order,[3] and codify interpretations and policies regarding permissible uses of algorithms by Retail Member Organizations.[4] The proposed rule change was published for comment in the **Federal Register** on February 13, 2024.[5] On March 21, 2024, pursuant to Section 19(b)(2) of the Act,[6] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[7] The Commission did not receive any comments. The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''Retail Order'' is defined in Exchange Rule 11.24(a)(2). *See infra* section II.

[4] The term ''Retail Member Organization'' (or ''RMO'') is defined in Exchange Rule 11.24(a)(1) to mean a member of the Exchange (or a division thereof) that has been approved by the Exchange under Exchange Rule 11.24 to submit Retail Orders.

[5] *See* Securities Exchange Act Release No. 99489 (February 7, 2024), 89 FR 10138 (''Notice'').

[6] 15 U.S.C. 78s(b)(2).

[7] *See* Securities Exchange Act Release No. 99819, 89 FR 21294 (March 27, 2024) (designating May 13, 2024, as the date by which the Commission shall either approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change).

Act [8] to determine whether to approve or disapprove the proposed rule change.

II. Description of the Proposed Rule Change [9]

Currently, the Exchange operates a retail price improvement program (''Retail Price Improvement Program'' or ''Program'') as an alternative venue for the execution of retail orders pursuant to Exchange Rule 11.24. Under the Program, RMOs may submit Retail Orders representing orders from retail investors to the Exchange. Pursuant to Exchange Rule 11.24(a)(2), a Retail Order is an agency order or riskless principal that meets the criteria of FINRA Rule 5320.03 that originates from a natural person and is submitted to the Exchange by a Retail Member Organization, provided that no change is made to the terms of the order with respect to price or side of market and the order does not originate from a trading algorithm or any other computerized methodology.[10] All Exchange Users [11] are permitted to submit Retail Price Improvement Orders, which express firm interest to price improve on the best protected bid or offer by at least $0.001 or more per share.[12] The Exchange disseminates a ''Retail Liquidity Identifier'' that reflects the symbol for a particular security and the side (buy or sell) of the Retail Price Improvement Order interest, but does not include the price or size of such interest.[13] In addition to its Retail Price Improvement Program, the Exchange states that it offers retail-only pricing incentives.[14]

The Exchange states it has received member feedback that its rule is unclear as to whether the use of algorithms or other computerized methodologies is permitted when submitting individual investors' orders to the Exchange,[15] and proposes to amend its definition of Retail Order to provide that the use of an algorithm to submit orders to the Exchange on behalf of a retail investor does not automatically preclude an RMO from designating such orders as ''Retail Orders.'' [16] The Exchange proposes that use of an algorithm to submit a Retail Order would be permissible provided that the order, or investment criteria for the order, originates from a natural person, such as the investor themselves, or a natural person on behalf of a retail investor (such as a financial advisor or trader).[17] The Exchange states that the proposed definition could encourage additional members to become RMOs and route their Retail Orders to the Exchange, and that if more members chose to become RMOs, there will be additional opportunities to interact with retail order flow, which is likely to incentivize more retail liquidity provision, as it is generally considered preferable to trade with retail orders than with orders of professional investors that are typically more informed regarding short-term price movements.[18]

In connection with the proposed amendments to its definition of Retail Order, the Exchange is proposing to adopt several Interpretations and Policies to describe: (1) the meaning of the term ''retail investor'' as used in the definition, (2) the meaning of the term ''natural person'' as used in the definition, (3) permissible uses of algorithms when entering Retail Orders onto the Exchange, and (4) when an RMO may amend a Retail Order's price or side. First, the Exchange is proposing Interpretation and Policy .01 to describe that the term ''retail investor'' is intended to refer to a non-professional, individual investor that invests money in their own account held at a brokerage firm or online brokerage firm, or an account held in corporate form for the benefit of an individual or group of related family members, and whose investment goals are mainly saving for retirement or education, generating income, or growing wealth over the long term.[19]

Second, the Exchange is proposing to adopt Interpretation and Policy .02 to describe the meaning of the term ''natural person'' as referenced in the Exchange's proposed definition of Retail Order. The Exchange states that it intends for the term ''natural person'' to refer to a human who enters an order or investment criteria for an order, and that this individual may be the retail investor him/herself, or a natural person entering the order on behalf of a retail investor, such as a financial advisor or trader.[20] According to the Exchange, this will help to ensure that only bona fide retail orders are submitted to the Exchange as Retail Orders by making clear that orders generated automatically by an algorithm, without human intervention, shall not be considered Retail Orders.[21]

Third, the Exchange states that it seeks to ensure that only bona fide retail flow is designated as a Retail Order and does not intend for professional investors and professional trading firms to avail themselves of the benefits provided to RMOs by the Exchange and is therefore proposing to adopt Interpretation and Policy .03 to describe how an RMO can permissibly utilize an algorithm when entering Retail Orders onto the Exchange. The Exchange states that an RMO could utilize an algorithm to enter individual investors' orders onto the Exchange, and permissibly designate such orders as Retail Orders, provided the order or investment criteria used to generate an order originates from a natural person, such as the retail investor him/herself, or a

[8] 15 U.S.C. 78s(b)(2)(B).

[9] For a full description of the proposed rule change, refer to the Notice, *supra* note 5. The text of the Exchange's proposed Rule 11.24(a)(2) and Interpretations and Policies .01–.04 is available on the Commission's website at *https://www.sec.gov/files/rules/sro/cboebyx/2024/34-99489-ex5.pdf.*

[10] Additionally, pursuant to Rule 11.24(a)(2), a Retail Order is an Immediate or Cancel Order and shall operate in accordance with paragraph (f) of Rule 11.24, and may be an odd lot, round lot, or mixed lot. Paragraph (f) of Rule 11.24 provides that an RMO can designate how a Retail Order will interact with available contra-side interest, such as whether, if the order does not execute against price improving interest, it is available to execute other interest in the Exchange's trading system and whether or not it may be routed.

[11] Pursuant to Exchange Rule 1.5(cc), a ''User'' is any member of sponsored participant who is authorized to access the Exchange's electronic communications and trading system.

[12] Pursuant to Exchange Rule 11.24(a)(3), a ''Retail Price Improvement Order'' or ''RPI Order'' consists of non-displayed interest on the Exchange that is priced better than the Protected NBB or Protected NBO by at least $0.001 and that is identified as such. The System will monitor whether RPI buy or sell interest, adjusted by any offset and subject to the ceiling or floor price, is eligible to interact with incoming Retail Orders. An RPI Order remains non-displayed in its entirety (the buy or sell interest, the offset, and the ceiling or floor). Additionally, an RPI Order may also be entered in a sub-penny increment with an explicit limit price. Any User is permitted, but not required, to submit RPI Orders, and an RPI Order may be an odd lot, round lot or mixed lot. Exchange Rule 11.24(a)(3).

[13] Exchange Rule 11.24(e).

[14] *See* Notice, *supra* note 5, at 10138.

[15] *Id.*

[16] *Id.* at 10139.

[17] *Id.* Pursuant to proposed Exchange Rule 11.24(a)(2), a Retail Order would be defined as an agency or riskless principal order that meets the criteria of FINRA Rule 5320.03, and would require a Retail Order to originate from a natural person, such as the retail investors themselves, or by a natural person on behalf of a retail investor, and be submitted to the Exchange by a Retail Member Organization. In submitting a Retail Order to the Exchange, a Retail Member Organization may utilize an algorithm or other computerized methodology, provided the terms or investment criteria of the order originate from a retail investor her/himself, or a natural person on behalf of a retail investor, and the algorithm or other computerized methodology does not change the terms or investment criteria of the Retail Order with respect to price or side.

[18] *Id.*

[19] *Id.* According to the Exchange, the term ''retail investor'' would not be intended to include individual investors that engage in more professional trading strategies designed to profit from bid-ask spreads, short-term price movements, and arbitrage, or in trading behavior where multiple buy and sell orders are entered over a short period of time based on market conditions. *Id.* at 10140.

[20] *Id.*

[21] *Id.*

natural person on behalf of a retail investor, and is submitted to the Exchange for execution by an RMO.[22] The Exchange states that, conversely, orders automatically generated and submitted to the Exchange by an algorithm based on factors such as market conditions and price movements, which do not originate from a manual entry of order terms or investment criteria by a natural person, shall not be considered Retail Orders.[23]

Fourth, the Exchange is proposing to adopt Interpretation and Policy .04 to provide that post-order entry an RMO may algorithmically amend the Retail Order's price or size provided such amendments are made for the purposes of seeking better execution, enhancing execution quality, or minimizing market impact, despite the provision in the Exchange's proposed definition of Retail Order that would otherwise prohibit the changing of the price or side of a Retail Order.[24] The Exchange proposes that such order amendments may also be made manually by a natural person who entered the order on behalf of the retail investor. Pursuant to proposed Interpretation and Policy .04, the purpose of the prohibition on changing the terms of an order in Exchange Rule 11.24(a)(2) is to prevent RMOs from utilizing algorithms that trade in a manner more appropriate for professional trading.[25]

The Exchange states that by routing Retail Orders to the Exchange, RMOs and their retail investors will benefit from the Exchange's retail-only pricing incentives, as well as increased price improvement opportunities offered by the Exchange's Retail Price Improvement Program.[26] In support of its proposal, the Exchange also states that it has in place robust protections to ensure only bona fide retail orders are designated as ''Retail Orders,'' and that the proposed amendments will augment the Exchange's existing RMO framework.[27]

III. Proceedings to Determine Whether to Approve or Disapprove SR–CboeBYX–2024–004, and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act[28] to determine whether the proposed rule change should be approved or disapproved. Institution of such proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide additional comment on the proposed rule change to inform the Commission's analysis of whether to approve or disapprove the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,[29] the Commission is providing notice of the grounds for disapproval under consideration. As described above, the Exchange has proposed to amend its definition of Retail Order and adopt related Interpretations and Policies describing: (1) the term ''retail investor' as used therein, (2) the term ''natural person'' as used therein, (3) permissible uses of algorithms when entering Retail Orders onto the Exchange, and (4) when an RMO may amend a Retail Order's price or side. The Commission is instituting proceedings to allow for additional analysis of, and input from commenters with respect to, the proposed rule change's consistency with the Act, and in particular, Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest; and not be designed to permit unfair discrimination between customers, issuers, brokers or dealers.[30]

The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, which are set forth in the Notice, in addition to any other comments they may wish to submit about the proposed rule change. In particular, the Commission seeks comment on the following questions and asks commenters to submit data where appropriate to support their views:

1. The Exchange states that it ''seeks to clarify precisely how Retail Orders may be entered onto the Exchange by RMOs through the use of algorithms.'' [31] What are commenters' views on whether the Exchange has described with sufficient clarity its proposed new definition of Retail Order and related Interpretations and Policies, including with respect to the circumstances under which (i) algorithms and computerized methodologies would be permitted for the submission of Retail Orders, and (ii) a Retail Member Organization would be permitted to change the terms of a Retail Order with respect to price and side, either manually or algorithmically? Why or why not?

2. The Exchange states that the proposed rule change will ''ensure that only bona fide retail orders are able to take advantage of the benefits provided to Retail Orders by the Exchange.'' [32] What are commenters' views on whether the proposed rule change would ensure that only bona fide retail orders receive retail-only benefits provided by the Exchange? [33] Why or why not? Do commenters believe the proposed rule change would impact the extent to which market participants

[22] *Id.* The Exchange states that acceptable uses of algorithms by an RMO would include, but not be limited to: a smart order router to route the Retail Order to the Exchange for execution; a smart order router to assess trading venues for the best priced quotation and liquidity prior to routing the Retail Order to the Exchange; an order management system, smart order router, or other functionality to change the terms an order to seek a better execution price; use of an order management system to assist with portfolio rebalancing and asset reallocation for the accounts of retail investors; and a retail investor's use of automated investment management tools offered by RMOs to manage their assets based on their goals and risk tolerance (*i.e.* robo-advisory solutions). *Id.*

[23] *Id.* at 10141. The Exchange states that examples of such algorithms would include, but not be limited to, algorithms developed for market-making, high-frequency trading, liquidity provision, arbitrage, hedging, or proprietary trading. In addition to the fact that such orders do not typically originate from a natural person, entities engaging in such trading strategies are not typically doing so for the account of a retail investor. *Id.*

[24] *Id. See also supra* note 16 describing the Exchange's proposed definition of Retail Order. The Exchange states that accordingly, an RMO may utilize an algorithm to add a limit price to an unpriced order, amend an order's price or size to manage an order's marketability or mitigate the risk of receiving executions at aberrant prices, or adjust the price or size of an order as market conditions or trading objectives may dictate. *See* Notice, *supra* note 5, at 10141.

[25] Proposed Interpretation and Policy .04 to Exchange Rule 11.24.

[26] *See* Notice, *supra* note 5, at 10144.

[27] *See id.* at 10142.

[28] 15 U.S.C. 78s(b)(2)(B).

[29] *Id.*

[30] 15 U.S.C. 78f(b)(5).

[31] *See* Notice, *supra* note 5, at 10143.

[32] *Id.*

[33] In approving the Exchange's existing definition of Retail Order, the Commission stated its belief ''that the [Retail Price Improvement] Program is sufficiently tailored to provide the benefits of potential price improvement only to bona fide retail order flow originating from natural persons.'' Securities Exchange Act Release No. 68303 (November 27, 2012) 77 FR 71652, 71656 (December 3, 2012) (SR–BYX–2012–19) (approving the Exchange's proposed rule change to adopt a retail price improvement program on a pilot basis). The Commission later approved the Exchange's proposal to make the program permanent. Securities Exchange Act Release No. 87154 (September 30, 2019), 84 FR 53183 (October 4, 2019) (SR–CboeBYX–2019–014).

provide Retail Price Improvement Orders? If so, how?

IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their data, views, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposed rule change, is consistent with Sections 6(b)(5) or any other provision of the Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of data, views, and arguments, the Commission will consider, pursuant to Rule 19b–4 under the Act,[34] any request for an opportunity to make an oral presentation.[35]

Interested persons are invited to submit written data, views, and arguments regarding whether the proposed rule change should be approved or disapproved by June 7, 2024. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by June 21, 2024. The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, in addition to any other comments they may wish to submit about the proposed rule change.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–CboeBYX–2024–004 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–CboeBYX–2024–004. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeBYX–2024–004 and should be submitted by June 7, 2024. Rebuttal comments should be submitted by June 21, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[36]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–10822 Filed 5–16–24; 8:45 am]

BILLING CODE 8011–01–P

[34] 17 CFR 240.19b–4.

[35] Section 19(b)(2) of the Act, as amended by the Securities Acts Amendments of 1975, Public Law 94–29 (Jun. 4, 1975), grants to the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Acts Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

[36] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100115; File No. SR–CboeBZX–2024–007]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Order Instituting Proceedings To Determine Whether To Approve or Disapprove Proposed Rule Change To Amend the Definition of Retail Order, and Codify Interpretations and Policies Regarding Permissible Uses of Algorithms by RMOs

May 13, 2024.

I. Introduction

On January 25, 2024, Cboe BZX Exchange, Inc (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend the definition of Retail Order,[3] and codify interpretations and policies regarding permissible uses of algorithms by Retail Member Organizations.[4] The proposed rule change was published for comment in the **Federal Register** on February 13, 2024.[5] On March 21, 2024, pursuant to Section 19(b)(2) of the Act,[6] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[7] The Commission did not receive any comments. The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act[8] to determine whether to approve or disapprove the proposed rule change.

II. Description of the Proposed Rule Change[9]

Currently, the Exchange operates a retail attribution program (''Retail

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''Retail Order'' is defined in Exchange Rule 11.25(a)(2). *See infra* section II.

[4] The term ''Retail Member Organization'' (or ''RMO'') is defined in Exchange Rule 11.25(a)(1) to mean a member of the Exchange (or a division thereof) that has been approved by the Exchange under Exchange Rule 11.25 to submit Retail Orders.

[5] *See* Securities Exchange Act Release No. 99488 (February 7, 2024), 89 FR 10121 (''Notice'').

[6] 15 U.S.C. 78s(b)(2).

[7] *See* Securities Exchange Act Release No. 99815, 89 FR 21290 (March 27, 2024) (designating May 13, 2024, as the date by which the Commission shall either approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change).

[8] 15 U.S.C. 78s(b)(2)(B).

[9] For a full description of the proposed rule change, refer to the Notice, *supra* note 5. The text

Continued

Attribution Program'' or ''Program'') pursuant to Exchange Rule 11.25. Under the Program, RMOs may designate a Retail Order to be identified as such on the Exchange's proprietary feeds, either on an order-by-order or port-by-port basis. Pursuant to Exchange Rule 11.25(a)(2), a Retail Order is an agency order or riskless principal that meets the criteria of FINRA Rule 5320.03 that originates from a natural person and is submitted to the Exchange by a Retail Member Organization, provided that no change is made to the terms of the order with respect to price or side of market and the order does not originate from a trading algorithm or any other computerized methodology.

The Exchange states it has received member feedback that its rule is unclear as to whether the use of algorithms or other computerized methodologies is permitted when submitting individual investors' orders to the Exchange,[10] and proposes to amend its definition of Retail Order to provide that the use of an algorithm to submit orders to the Exchange on behalf of a retail investor does not automatically preclude an RMO from designating such orders as ''Retail Orders.'' [11] The Exchange proposes that use of an algorithm to submit a Retail Order would be permissible provided that the order, or investment criteria for the order, originates from a natural person, such as the investor themselves, or a natural person on behalf of a retail investor (such as a financial advisor or trader).[12] The Exchange states that by amending the Retail Order definition, more RMOs may choose to avail themselves of the benefits offered by the Exchange's Retail Attribution Program, and that the enhanced opportunity to interact with retail order flow is likely to incentivize more retail liquidity provision, as it is generally considered preferable to trade with retail orders than with orders of professional investors that are typically more informed regarding short-term price movements.[13]

In connection with the proposed amendments to its definition of Retail Order, the Exchange is proposing to adopt several Interpretations and Policies to describe: (1) the meaning of the term ''retail investor'' as used in the definition, (2) the meaning of the term ''natural person'' as used in the definition, (3) permissible uses of algorithms when entering Retail Orders onto the Exchange, and (4) when an RMO may amend a Retail Order's price or side. First, the Exchange is proposing Interpretation and Policy .01 to describe that the term ''retail investor'' is intended to refer to a non-professional, individual investor that invests money in their own account held at a brokerage firm or online brokerage firm, or an account held in corporate form for the benefit of an individual or group of related family members, and whose investment goals are mainly saving for retirement or education, generating income, or growing wealth over the long term.[14]

Second, the Exchange is proposing to adopt Interpretation and Policy .02 to describe the meaning of the term ''natural person'' as referenced in the Exchange's proposed definition of Retail Order. The Exchange states that it intends for the term ''natural person'' to refer to a human who enters an order or investment criteria for an order, and that this individual may be the retail investor him/herself, or a natural person entering the order on behalf of a retail investor, such as a financial advisor or trader.[15] According to the Exchange, this will help to ensure that only bona fide retail orders are submitted to the Exchange as Retail Orders by making clear that orders generated automatically by an algorithm, without human intervention, shall not be considered Retail Orders.[16]

Third, the Exchange states that it seeks to ensure that only bona fide retail flow is designated as a Retail Order and does not intend for professional investors and professional trading firms to avail themselves of the benefits provided to RMOs by the Exchange, and is therefore proposing to adopt Interpretation and Policy .03 to describe how an RMO can permissibly utilize an algorithm when entering Retail Orders onto the Exchange. The Exchange states that an RMO could utilize an algorithm to enter individual investors' orders onto the Exchange, and permissibly designate such orders as Retail Orders, provided the order or investment criteria used to generate an order originates from a natural person, such as the retail investor him/herself, or a natural person on behalf of a retail investor, and is submitted to the Exchange for execution by an RMO.[17] The Exchange states that, conversely, orders automatically generated and submitted to the Exchange by an algorithm based on factors such as market conditions and price movements, which do not originate from a manual entry of order terms or investment criteria by a natural person, shall not be considered Retail Orders.[18]

Fourth, the Exchange is proposing to adopt Interpretation and Policy .04 to provide that post-order entry an RMO may algorithmically amend the Retail Order's price or size provided such amendments are made for the purposes of seeking better execution, enhancing execution quality, or minimizing market impact, despite the provision in the Exchange's proposed definition of Retail Order that would otherwise prohibit the changing of the price or side of a Retail Order.[19] The Exchange proposes that such order amendments may also be

of the Exchange's proposed Rule 11.25(a)(2) and Interpretations and Policies .01–.04 is available on the Commission's website at *https://www.sec.gov/files/rules/sro/cboebzx/2024/34-99488-ex5.pdf*.

[10] *See* Notice, *supra* note at 10122.

[11] *Id.*

[12] *Id.* Pursuant to proposed Exchange Rule 11.25(a)(2), a Retail Order would be defined as an agency or riskless principal order that meets the criteria of FINRA Rule 5320.03, and would require a Retail Order to originate from a natural person, such as the retail investors themselves, or by a natural person on behalf of a retail investor, and be submitted to the Exchange by a Retail Member Organization. In submitting a Retail Order to the Exchange, a Retail Member Organization may utilize an algorithm or other computerized methodology, provided the terms or investment criteria of the order originate from a retail investor her/himself, or a natural person on behalf of a retail investor, and the algorithm or other computerized methodology does not change the terms or investment criteria of the Retail Order with respect to price or side.

[13] *Id.* at 10122–23.

[14] *Id.* at 10123. According to the Exchange, the term ''retail investor'' would not be intended to include individual investors that engage in more professional trading strategies designed to profit from bid-ask spreads, short-term price movements, and arbitrage, or in trading behavior where multiple buy and sell orders are entered over a short period of time based on market conditions. *Id.*

[15] *Id.*

[16] *Id.*

[17] *Id.* at 10124. The Exchange states that acceptable uses of algorithms by an RMO would include, but not be limited to: a smart order router to route the Retail Order to the Exchange for execution; a smart order router to assess trading venues for the best priced quotation and liquidity prior to routing the Retail Order to the Exchange; an order management system, smart order router, or other functionality to change the terms an order to seek a better execution price; use of an order management system to assist with portfolio rebalancing and asset reallocation for the accounts of retail investors; and a retail investor's use of automated investment management tools offered by RMOs to manage their assets based on their goals and risk tolerance (*i.e.* robo-advisory solutions). *Id.*

[18] *Id.* at 10125. The Exchange states that examples of such algorithms would include, but not be limited to, algorithms developed for market-making, high-frequency trading, liquidity provision, arbitrage, hedging, or proprietary trading. In addition to the fact that such orders do not typically originate from a natural person, entities engaging in such trading strategies are not typically doing so for the account of a retail investor. *Id.*

[19] *Id. See also supra* note 12 describing the Exchange's proposed definition of Retail Order. The Exchange states that accordingly, an RMO may utilize an algorithm to add a limit price to an unpriced order, amend an order's price or size to manage an order's marketability or mitigate the risk of receiving executions at aberrant prices, or adjust the price or size of an order as market conditions or trading objectives may dictate. *See* Notice, *supra* note 5, at 10125.

made manually by a natural person who entered the order on behalf of the retail investor. Pursuant to proposed Interpretation and Policy .04, the purpose of the prohibition on changing the terms of an order in Exchange Rule 11.25(a)(2) is to prevent RMOs from utilizing algorithms that trade in a manner more appropriate for professional trading.[20]

The Exchange states that by routing Retail Orders to the Exchange, RMOs and their retail investors will benefit from the Exchange's retail-only pricing incentives.[21] In support of its proposal, the Exchange also states that it has in place robust protections to ensure only bona fide retail orders are designated as ''Retail Orders,'' and that the proposed amendments will augment the Exchange's existing RMO framework.[22]

III. Proceedings To Determine Whether To Approve or Disapprove SR–CboeBZX–2024–007, and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act [23] to determine whether the proposed rule change should be approved or disapproved. Institution of such proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide additional comment on the proposed rule change to inform the Commission's analysis of whether to approve or disapprove the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,[24] the Commission is providing notice of the grounds for disapproval under consideration. As described above, the Exchange has proposed to amend its definition of Retail Order and adopt related Interpretations and Policies describing: (1) the term ''retail investor'' as used therein, (2) the term ''natural person'' as used therein, (3) permissible uses of algorithms when entering Retail Orders onto the Exchange, and (4) when an RMO may amend a Retail Order's price or side. The Commission is instituting proceedings to allow for additional analysis of, and input from commenters with respect to, the proposed rule change's consistency with the Act, and in particular, Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest; and not be designed to permit unfair discrimination between customers, issuers, brokers or dealers.[25]

The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, which are set forth in the Notice, in addition to any other comments they may wish to submit about the proposed rule change. In particular, the Commission seeks comment on the following questions and asks commenters to submit data where appropriate to support their views:

1. The Exchange states that it ''seeks to clarify precisely how Retail Orders may be entered onto the Exchange by RMOs through the use of algorithms.[26] What are commenters' views on whether the Exchange has described with sufficient clarity its proposed new definition of Retail Order and related Interpretations and Policies, including with respect to the circumstances under which (i) algorithms and computerized methodologies would be permitted for the submission of Retail Orders, and (ii) a Retail Member Organization would be permitted to change the terms of a Retail Order with respect to price and side, either manually or algorithmically? Why or why not?

2. The Exchange states that the proposed rule change will ''ensure that only bona fide retail orders are able to take advantage of the benefits provided to Retail Orders by the Exchange.'' [27] What are commenters' views on whether the proposed rule change would ensure that only bona fide retail orders benefit from retail-only pricing incentives [28] provided by the Exchange? Why or why not?

IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their data, views, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposed rule change, is consistent with Sections 6(b)(5) or any other provision of the Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of data, views, and arguments, the Commission will consider, pursuant to Rule 19b–4 under the Act,[29] any request for an opportunity to make an oral presentation.[30]

Interested persons are invited to submit written data, views, and arguments regarding whether the proposed rule change should be approved or disapproved by June 7, 2024. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by June 21, 2024. The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, in addition to any other comments they may wish to submit about the proposed rule change.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeBZX–2024–007 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–CboeBZX–2024–007. 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 (*https://www.sec.gov/*

[20] Proposed Interpretation and Policy .04 to Exchange Rule 11.25.

[21] *See* Notice, *supra* note 5, at 10127.

[22] *See id.* at 10126.

[23] 15 U.S.C. 78s(b)(2)(B).

[24] *Id.*

[25] 15 U.S.C. 78f(b)(5).

[26] *See* Notice, *supra* note 5, at 10127.

[27] *Id.*

[28] *See* Cboe U.S. Equities Fee Schedule for BZX available at *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/.*

[29] 17 CFR 240.19b–4.

[30] Section 19(b)(2) of the Act, as amended by the Securities Acts Amendments of 1975, Public Law 94–29 (Jun. 4, 1975), grants to the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Acts Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeBZX–2024–007 and should be submitted by June 7, 2024. Rebuttal comments should be submitted by June 21, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–10824 Filed 5–16–24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100112; File No. SR–MEMX–2024–16]

Self-Regulatory Organizations; MEMX LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange's Fee Schedule Concerning Transaction Pricing

May 13, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on April 30, 2024, MEMX LLC (''MEMX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing with the Commission a proposed rule change to amend the Exchange's fee schedule applicable to Members[3] (the ''Fee Schedule'') pursuant to Exchange Rules 15.1(a) and (c). The Exchange proposes to implement the changes to the Fee Schedule pursuant to this proposal on May 1, 2024. The text of the proposed rule change is provided in Exhibit 5.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Fee Schedule to: (1) increase the maximum combined rebate per share provided by the Exchange; (2) modify the Liquidity Provision Tiers by modifying the required criteria under both Liquidity Provision Tiers 1 and 2; (3) modify Liquidity Removal Tier 1 by modifying the required criteria under such tier; (4) modify Non-Display Add Tier 1 by modifying the required criteria under such tier; (5) modify NBBO Setter Tier 1 by modifying the required criteria under such tier; (6) modify Cross Asset Tier 2 by modifying the required criteria under such tier; and (7) modify the DLI Additive Tier by modifying the required criteria under such tier to correspond with the proposed changes to Liquidity Provision Tiers 1 and 2, each as further described below.

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 16 registered equities exchanges, as well as a number of alternative trading systems and other off-exchange venues, to which market participants may direct their order flow. Based on publicly available information, no single registered equities exchange currently has more than approximately 16% of the total market share of executed volume of equities trading.[4] Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow, and the Exchange currently represents approximately 2.4% of the overall market share.[5] The Exchange in particular operates a ''Maker-Taker'' model whereby it provides rebates to Members that add liquidity to the Exchange and charges fees to Members that remove liquidity from the Exchange. The Fee Schedule sets forth the standard rebates and fees applied per share for orders that add and remove liquidity, respectively. Additionally, in response to the competitive environment, the Exchange also offers tiered pricing, which provides Members with opportunities to qualify for higher rebates or lower fees where certain volume criteria and thresholds are met. Tiered pricing provides an incremental incentive for Members to strive for higher tier levels, which provides increasingly higher benefits or discounts for satisfying increasingly more stringent criteria.

Maximum Combined Rebate per Share

The Exchange offers various volume-based tiers which provide qualifying Members with enhanced or additive rebates (which apply in addition to the otherwise applicable rebate) with respect to qualifying executions where certain volume criteria and thresholds are met. The Exchange caps the maximum combined rebate which a Member can achieve when such Member achieves one or more additive rebates. Currently, the Exchange provides a maximum combined rebate of $0.0036 per share. Now, the Exchange proposes to increase the maximum combined rebate per share to $0.0037. Specifically, the Exchange will modify the final bullet in the ''Notes'' section of its Fee Schedule to change the

[31] 17 CFR 200.30–3(a)(57).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Exchange Rule 1.5(p).

[4] Market share percentage calculated as of April 30, 2024. The Exchange receives and processes data made available through consolidated data feeds (*i.e.,* CTS and UTDF).

[5] *Id.*

maximum combined rebate per share from $0.0036 to $0.0037.

The Exchange believes that increasing the maximum combined rebate per share will encourage market participants to strive to achieve the criteria under one or more additive rebate tiers by raising the rebate cap applicable to such tiers. The Exchange offers three additive rebates, namely, the NBBO Setter Tier (further explained below), the Tape B Volume Tier (which provides an additive rebate for executions of Added Displayed Volume [6] excluding Retail Orders in securities priced over $1.00 per share), and the DLI Additive Rebate (which provides an additive rebate for qualifying Members' executions of Added Displayed Volume other than Retail Orders that otherwise qualify for the applicable rebate under Liquidity Provision Tier 1 or Liquidity Provision Tier 2 as well as the applicable criteria under DLI Additive Rebate Tier 1). The Exchange believes that the increase in the maximum combined rebate provides an incremental incentive for Members to strive for higher volume thresholds to receive additional enhanced rebates which otherwise would have been capped at a lower rebate per share for such executions and, as such, is intended to encourage Members to maintain or increase their order flow, primarily in the form of liquidity-adding volume, to the Exchange, thereby contributing to a deeper and more liquid market to the benefit of all Members and market participants. The Exchange believes that the maximum combined rebate, as modified by the proposed changes described above, reflects a reasonable and competitive pricing structure that is right-sized and consistent with the Exchange's overall pricing philosophy of encouraging added and/or displayed liquidity.

Liquidity Provision Tiers

The Exchange currently provides a base rebate of $0.0015 per share for executions of Added Displayed Volume in securities priced at or above $1.00 per share. The Exchange also currently offers Liquidity Provision Tiers 1–5 under which a Member may receive an enhanced rebate for executions of Added Displayed Volume by achieving the corresponding required volume criteria for each such tier. The Exchange now proposes to modify the Liquidity Provision Tiers by modifying the required criteria under Liquidity Provision Tier 1 and modifying the required criteria under Liquidity Provision Tier 2, as further described below.

First, with respect to Liquidity Provision Tier 1, the Exchange currently provides an enhanced rebate of $0.0033 per share for executions of Added Displayed Volume in securities priced at or above $1.00 per share for Members that qualify for such tier by achieving: (1) an ADAV [7] (excluding Retail Orders) that is equal to or greater than 0.45% of the TCV; [8] or (2) an ADAV that is equal to or greater than 0.30% of the TCV and a Non-Displayed ADAV [9] that is equal to or greater than 7,000,000 shares.[10] The Exchange now proposes to modify the required criteria under Liquidity Provision Tier 1 such that a Member would qualify for such tier by achieving: (1) an ADAV (excluding Retail Orders) that is equal to or greater than 0.45% of the TCV; or (2) an ADAV that is equal to or greater than 0.30% of the TCV and a Non-Displayed ADAV that is equal to or greater than 6,000,000 shares. Thus, such proposed change would keep criteria (1) intact and decrease the Non-Displayed ADAV requirement in criteria (2) from 7,000,000 shares to 6,000,000 shares. The Exchange is not proposing to change the rebate provided under such tier.

With respect to Liquidity Provision Tier 2, the Exchange currently provides an enhanced rebate of $0.0032 per share for executions of Added Displayed Volume in securities priced at or above $1.00 per share for Members that qualify for such tier by achieving: (1) an ADAV that is equal to or greater than 0.25% of the TCV and a Non-Displayed ADAV that is equal to or greater than 4,000,000 shares; or (2) an ADAV that is equal to or greater than 0.35% of the TCV.[11] Now, the Exchange proposes to modify the required criteria under Liquidity Provision Tier 2 such that Members qualify for such tier by achieving (1) an ADAV that is equal to or greater than 0.20% of the TCV and (2) an ADV [12] that is equal to or greater than 0.35% of the TCV. Thus, such proposed change would replace the existing criteria for Liquidity Provision Tier 2 with new criteria. The Exchange is not proposing to change the rebate provided under such tier.

The Exchange believes that the tiered pricing structure for executions of Added Displayed Volume under the proposed modified Liquidity Provision Tiers 1 and 2 provides an incremental incentive for Members to strive for higher volume thresholds to receive higher enhanced rebates for such executions and, as such, is intended to encourage Members to maintain or increase their order flow, primarily in the form of liquidity-adding volume, to the Exchange, thereby contributing to a deeper and more liquid market to the benefit of all Members and market participants. Specifically, the Exchange believes that, after giving effect to the proposed changes described above, the rebate for executions of Added Displayed Volume provided under each of the Liquidity Provision Tiers remains commensurate with the corresponding required criteria under each such tier and is reasonably related to the market quality benefits that each such tier is designed to achieve.

Liquidity Removal Tier 1

The Exchange currently charges a standard fee of $0.0030 per share for executions of orders in securities priced at or above $1.00 per share that remove liquidity from the Exchange (such orders, ''Removed Volume''). The Exchange also currently offers Liquidity Removal Tiers under which qualifying Members are charged a discounted fee by achieving the corresponding required volume criteria for each such tier. The Exchange now proposes to modify Liquidity Removal Tier 1 by changing the required criteria under such tier. Currently, a Member qualifies for Liquidity Removal Tier 1 by achieving one of the following two alternative criteria: (1) an ADV that is equal to or greater than 0.60% of the TCV; or (2) a

[6] The base rebate for executions of Added Displayed Volume is referred to by the Exchange on the Fee Schedule under the existing description ''Added displayed volume'' with a Fee Code of ''B'', ''D'' or ''J'', as applicable, on execution reports.

[7] As set forth on the Fee Schedule, ''ADAV'' means the average daily added volume calculated as the number of shares added per day, which is calculated on a monthly basis, and ''Displayed ADAV'' means ADAV with respect to displayed orders.

[8] As set forth on the Fee Schedule, ''TCV'' means total consolidated volume calculated as the volume reported by all exchanges and trade reporting facilities to a consolidated transaction reporting plan for the month for which the fees apply.

[9] As set forth on the Fee Schedule, ''Non-Displayed ADAV'' means ADAV with respect to non-displayed orders (including orders subject to Display-Price Sliding that receive price improvement when executed and Midpoint Peg orders).

[10] The pricing for Liquidity Provision Tier 1 is referred to by the Exchange on the Fee Schedule under the existing description ''Added displayed volume, Liquidity Provision Tier 1'' with a Fee Code of ''B1'', ''D1'' or ''J1'', as applicable, to be provided by the Exchange on the monthly invoices provided to Members.

[11] The proposed pricing for Liquidity Provision Tier 2 is referred to by the Exchange on the Fee Schedule under the existing description ''Added displayed volume, Liquidity Provision Tier 2'' with a Fee Code of ''B2'', ''D2'' or ''J2'', as applicable, to be provided by the Exchange on the monthly invoices provided to Members.

[12] As set forth on the Fee Schedule, ''ADV'' means average daily volume calculated as the number of shares added or removed, combined, per day, which is calculated on a monthly basis.

Remove ADV [13] that is equal to or greater than 0.30% of the TCV.[14] Now, the Exchange proposes to modify Liquidity Removal Tier 1 such that a Member qualifies for such tier by achieving (1) an ADV that is equal to or greater than 0.70% of the TCV; or (2) a Remove ADV that is equal to or greater than 0.35% of the TCV. Specifically, the Exchange is changing the ADV percentage in criteria (1) to 0.70% and changing the Remove ADV percentage in criteria (2) to 0.35%. The Exchange is not proposing to change the rebate provided under such tier.

The proposed changes to the Liquidity Removal Tiers are designed to encourage Members to maintain or increase their order flow, including in the form of orders that remove liquidity, to the Exchange in order to qualify for the proposed discounted fee for executions of Removed Volume. While the Exchange's overall pricing philosophy generally encourages adding liquidity over removing liquidity, the Exchange believes that providing alternative criteria that are based on different types of volume that Members may choose to achieve, such as the proposed new criteria which includes a Remove ADV threshold, contributes to a more robust and well-balanced market ecosystem on the Exchange to the benefit of all Members.

Non-Display Add Tier 1

The Exchange currently offers Non-Display Add Tiers 1–4 under which a Member may receive an enhanced rebate for executions of Added Non-Displayed Volume in securities priced at or above $1.00 per share by achieving the corresponding required volume criteria for each such tier. The Exchange now proposes to modify the Non-Display Add Tiers by changing the criteria under Non-Display Add Tier 1. Currently, under Non-Display Add Tier 1, the Exchange provides an enhanced rebate of $0.0028 per share for executions of Added Non-Displayed Volume in securities priced at or above $1.00 per share for Members that qualify for such tier by achieving a Non-Displayed ADAV that is equal to or greater than 8,000,000 shares.[15] Now, the Exchange proposes to provide the same rebate for executions of Added Non-Displayed Volume in securities priced at or above $1.00 per share for Members that qualify for such tier by achieving a Non-Displayed ADAV that is equal to or greater than 6,000,000 shares. The Exchange is not proposing to change the rebate provided under such tier.

The purpose of lowering the Non-Displayed ADAV requirement to achieve Non-Display Add Tier 1 is to facilitate Members' ability to qualify for the rebate for executions of Added Non-Displayed Volume. The Exchange believes that more Members will be able to qualify for the rebate at the lower Non-Displayed ADAV share requirement, which the Exchange believes may encourage Members to maintain or increase their order flow. The Exchange believes that this will contribute to a deeper and more robust and well-balanced market ecosystem to the benefit of all Members and market participants. The Exchange believes that the Non-Display Add Tiers, as modified by the proposed changes described above, reflect a reasonable and competitive pricing structure that is right-sized and consistent with the Exchange's overall pricing philosophy of encouraging added and/or displayed liquidity. Specifically, the Exchange believes that, after giving effect to the proposed changes described above, the rebate for executions of Added Non-Displayed Volume provided under each of the Non-Display Add Tiers is commensurate with the corresponding required criteria under each such tier and is reasonably related to the market quality benefits that each such tier is designed to achieve.

NBBO Setter Tier

The Exchange currently offers NBBO Setter Tier 1 under which a Member may receive an additive rebate of $0.0002 per share for a qualifying Member's executions of Added Displayed Volume (other than Retail Orders) in securities priced at or above $1.00 per share that establish the NBBO and have a Fee Code B [16] (such orders, ''Setter Volume''), and an additive rebate of $0.0001 per share for executions of Added Displayed Volume (other than Retail Orders) that do not establish the NBBO (*i.e.,* Fee Codes D and J) [17] by achieving: (1) an ADAV with respect to orders with Fee Code B that is equal to or greater than 0.10% of the TCV; or (2) an ADAV with respect to orders with Fee Code B that is equal to or greater than 0.05% of the TCV or 5,000,000 shares and a Step-Up ADAV with respect to orders with a Fee Code B that is equal to or greater than 75% of the Member's March 2024 ADAV with respect to orders with a Fee Code B. Now, the Exchange proposes to modify the required criteria under NBBO Setter Tier 1 such that a Member would now qualify for such tier by achieving: (1) an ADAV with respect to orders with Fee Code B that is equal to or greater than 5,000,000 shares; or (2) an ADAV (excluding Retail Orders) that is equal to or greater than 0.30% of the TCV. The Exchange will also delete the reference in the footnote to the NBBO Setter Tier portion of the fee schedule which references the expiration of existing criteria (2) no later than September 30, 2024; since existing criteria (2) of the NBBO Setter Tier is being fully deleted and replaced with a new criteria (2), this footnote is no longer relevant. The Exchange is not proposing to change the amount of the additive rebates provided under the NBBO Setter Tier 1.

The Exchange believes that the proposed modified criteria provides an incremental incentive for Members to strive for higher ADAV on the Exchange to receive the additive rebate for qualifying executions of Added Displayed Volume under such tier, and thus, it is designed to encourage Members that do not currently qualify for such tier to increase their overall orders that add liquidity to the Exchange. The Exchange also believes that the criteria changes reflect a reasonable and competitive pricing structure that is right-sized and consistent with the Exchange's overall pricing philosophy of encouraging added and/or displayed liquidity. The

[13] As set forth on the Fee Schedule, ''Remove ADV'' means ADV with respect to orders that remove liquidity.

[14] The pricing for Liquidity Removal Tier 1 is referred to by the Exchange on the Fee Schedule under the existing description ''Removed volume from MEMX Book, Liquidity Removal Tier 1'' with a Fee Code of ''R1'' to be provided by the Exchange on the monthly invoices provided to Members. The Exchange notes that because the determination of whether a Member qualifies for a certain pricing tier for a particular month will not be made until after the month-end, the Exchange provides the Fee Codes otherwise applicable to such transactions on the execution reports provided to Members during the month and only designates the Fee Codes applicable to the achieved pricing tier on the monthly invoices, which are provided after such determination has been made, as the Exchange does for its tier-based pricing today.

[15] The pricing for Non-Display Add Tier 1 is referred to by the Exchange on the Fee Schedule under the existing description ''Added non-displayed volume, Non-Display Add Tier 1'' with a Fee Code of ''H1'', ''M1'' or ''P1'', as applicable, to be provided by the Exchange on the monthly invoices provided to Members.

[16] The Exchange notes that orders with Fee Code B include orders, other than Retail Orders, that establish the NBBO.

[17] The Exchange notes that orders with Fee Code J include orders, other than Retail Orders, that establish a new BBO on the Exchange that matches the NBBO first established on an away market. Orders with Fee Code D include orders that add displayed liquidity to the Exchange but that are not Fee Code B or J, and thus, orders with Fee Code B, D or J include all orders, other than Retail Orders, that add displayed liquidity to the Exchange.

Exchange believes that the proposed modified criteria would further incentivize increased order flow to the Exchange, thereby contributing to a deeper and more liquid market to the benefit of all Members.

Cross Asset Tiers

The Exchange currently offers Cross Asset Tiers 1, 2, and 3 under which a Member may receive an enhanced rebate for executions of Added Displayed Volume in securities priced at or above $1.00 per share by achieving the corresponding required volume criteria for such tier on the Exchange's equity options platform, MEMX Options. The Exchange now proposes to change the required criteria by which a Member may qualify for Cross Asset Tier 2, as described below.

Currently the Exchange provides an enhanced rebate of $0.0027 per share for executions of Added Displayed Volume for Members that qualify for such tier by achieving an Options ADAV [18] in the Market Maker [19] capacity that is equal to or greater than 150,000 contracts on MEMX Options. Now, the Exchange proposes to modify the required criteria under Cross Asset Tier 2 such that such that a Member would qualify for such tier by achieving an Options ADAV in the Market Maker capacity that is equal to or greater than 125,000 contracts on MEMX Options.

The proposed new criteria for Cross Asset Tier 2 is designed to facilitate additional Members to meet the Options ADAV requirements for such tier. The Exchange believes that the lowered requirements to meet the tier will incentivize Members to maintain or increase their order flow to the MEMX Options Exchange in the Market Maker capacity. The Exchange also believes that the new criteria will encourage greater participation on MEMX Equities by making it easier for Members to qualify for Cross Asset Tier 2 via their Options ADAV, thereby contributing to a deeper and more robust and well-balanced market ecosystem on the Exchange to the benefit of all Members and market participants.

Displayed Liquidity Initiative (''DLI'') Additive Rebate

The Exchange currently offers the DLI Additive Rebate Tier 1 under which a Member may receive an additive rebate for a qualifying Member's executions of Added Displayed Volume (other than Retail Orders) in securities priced at or above $1.00 per share that otherwise qualify for the applicable rebate under Liquidity Provision Tier 1 or Liquidity Provision Tier 2 as well as the applicable criteria under DLI Tier 1.[20] The Exchange now proposes to modify the DLI Additive Rebate Tier 1 by updating the required applicable criteria under Liquidity Provision Tiers 1 and 2 in accordance with this proposal. The purpose of these changes is to update the criteria to match the proposed changes to the applicable criteria under Liquidity Provision Tiers 1 and 2 which have been described above.

Currently, under DLI Additive Rebate Tier 1, the Exchange provides an additive rebate of $0.00005 per share for executions of Added Displayed Volume that first meet the criteria under DLI Tier 1, which include achieving: (1) an NBBO time of at least 25% in an average of at least 1,000 securities per trading day during the month; and (2) an ADAV that is equal to or greater than 0.10% of the TCV,[21] as well as the applicable criteria under Liquidity Provision Tier 1 or Liquidity Provision Tier 2. Under Liquidity Provision Tier 1, the Exchange is now proposing (as described above) Members will received the enhanced rebate by achieving: (1) an ADAV (excluding Retail Orders) that is equal to or greater than 0.45% of the TCV; or (2) an ADAV that is equal to or greater than 0.30% of the TCV and a Non-Displayed ADAV that is equal to or greater than 6,000,000 shares. Thus, now, the Exchange proposes to modify the criteria for the DLI Additive Rebate to correspond to the modifications to Liquidity Provision Tier 1 criteria described above. Under Liquidity Provision Tier 2, the Exchange is now proposing (as described above) that Members will receive the enhanced rebate by achieving: (1) an ADAV that is equal to or greater than 0.20% of the TCV and (2) an ADV that is equal to or greater than 0.35% of the TCV. Thus, now, the Exchange proposes to modify the criteria for the DLI Additive Rebate to correspond to the modifications to Liquidity Provision Tier 2 criteria described above. Again, the Exchange notes that Members qualify for the DLI Additive rebate by achieving both the criteria under DLI Tier 1 and either Liquidity Provision Tier 1 or Liquidity Provision Tier 2.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[22] in general, and with Sections 6(b)(4) and 6(b)(5) of the Act,[23] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As discussed above, the Exchange operates in a highly fragmented and competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient, and the Exchange represents only a small percentage of the overall market. The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and also recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [24]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue to reduce use of certain categories of products, in response to new or different pricing structures being introduced into the market. Accordingly, competitive forces constrain the Exchange's transaction fees and rebates, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable. The Exchange believes the proposal reflects a reasonable and competitive pricing structure designed to incentivize market participants to

[18] As set forth on the Fee Schedule, a Member's ''Options ADAV'' for purposes of equities pricing means the average daily added volume calculated as a number of contracts added on MEMX Options per day by the Member, which is calculated on a monthly basis.

[19] As set forth on the MEMX Options Fee Schedule, ''Market Maker'' applies to any order for the account of a registered Market Maker. ''Market Maker'' shall have the meaning set forth in Rule 16.1 of the MEMX Rulebook.

[20] This pricing is referred to by the Exchange on the Fee Schedule under the existing description ''DLI Additive Rebate'' with a Fee Code of ''q'' to be appended to the otherwise applicable Fee Code for qualifying executions.

[21] The enhanced rebate provided under DLI Tier 1 is $0.0031 per share for executions of Added Displayed Volume.

[22] 15 U.S.C. 78f.

[23] 15 U.S.C. 78f(b)(4) and (5).

[24] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

direct additional order flow to the Exchange, as well as to the Exchange's equity options platform, MEMX Options, which the Exchange believes would promote price discovery and enhance liquidity and market quality on the Exchange and on MEMX Options to the benefit of all Members and market participants.

The Exchange notes that volume-based incentives and discounts have been widely adopted by exchanges, including the Exchange, and are reasonable, equitable and not unfairly discriminatory because they are open to all members on an equal basis and provide additional benefits or discounts that are reasonably related to the value to an exchange's market quality associated with higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns, and the introduction of higher volumes of orders into the price and volume discovery process. The Exchange believes that raising the maximum combined rebate is reasonable, equitable, and not unfairly discriminatory as all Members are equally eligible to achieve rebates up to the maximum combined rebate on the Exchange. The Exchange believes that increasing the maximum rebate which Members can achieve will incentivize Members to maintain or increase their order flow to the Exchange, in order to qualify for multiple additive rebates offered by the Exchange, thus increasing liquidity and contributing to a deeper and more liquid market ecosystem on the Exchange. The Exchange believes that the Liquidity Provision Tiers 1 and 2, the Liquidity Removal Tier, the Non-Display Add Tier 1, the NBBO Setter Tier 1, Cross-Asset Tier 2, and DLI Additive Rebate, each as modified by the proposed changes to the required criteria under each such tier as described above, are reasonable, equitable and not unfairly discriminatory for these same reasons. Such tiers would provide Members with an incremental incentive to achieve certain volume thresholds on the Exchange (and in the case of the Cross Asset Tiers, MEMX Options), are available to all Members on an equal basis, and, as described above, are designed to encourage Members to maintain or increase their order flow, including in the form of displayed, non-displayed, liquidity-adding, liquidity-removing, and/or NBBO-setting orders to the Exchange in order to qualify for an enhanced rebate, as applicable, thereby contributing to a deeper, more liquid and well balanced market ecosystem on the Exchange to the benefit of all Members and market participants.

The Exchange also believes that the proposed changes to the criteria for Cross Asset Tier 2 are reasonable, equitably allocated and non-discriminatory with respect to all Members, as the ability to achieve the new criteria is available to all Members. Membership on MEMX Options is available to all market participants which would provide them with access to the benefits on MEMX Options provided by the proposal, even where a member of MEMX Options is not necessarily eligible for the proposed enhanced rebates on the Exchange. The Exchange also believes, as stated above, that the new criteria in Cross-Asset Tier 2 will encourage greater participation on MEMX Equities by qualifying participants, thereby contributing to a deeper and more robust and well-balanced market ecosystem on the Exchange to the benefit of all Members and market participants.

For the reasons discussed above, the Exchange submits that the proposal satisfies the requirements of Sections 6(b)(4) and 6(b)(5) of the Act [25] in that it provides for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities and is not designed to unfairly discriminate between customers, issuers, brokers, or dealers. As described more fully below in the Exchange's statement regarding the burden on competition, the Exchange believes that its transaction pricing is subject to significant competitive forces, and that the proposed fees and rebates described herein are appropriate to address such forces.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposal will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the proposal is intended to incentivize market participants to direct additional order flow to the Exchange, and to MEMX Options, thereby enhancing liquidity and market quality on the Exchange to the benefit of all Members and market participants. As a result, the Exchange believes the proposal would enhance its competitiveness as a market that attracts actionable orders, thereby making it a more desirable destination venue for its customers. For these reasons, the Exchange believes that the proposal furthers the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [26]

Intramarket Competition

As discussed above, the Exchange believes that the proposal would incentivize Members to submit additional order flow, including displayed, liquidity-adding and/or removing, and/or NBBO setting orders to both the Exchange and MEMX Options, thereby enhancing liquidity and market quality on the Exchange to the benefit of all Members, as well as enhancing the attractiveness of the Exchange as a trading venue, which the Exchange believes, in turn, would continue to encourage market participants to direct additional order flow to the Exchange. Greater liquidity benefits all Members by providing more trading opportunities and encourages Members to send additional orders to the Exchange, thereby contributing to robust levels of liquidity, which benefits all market participants. The opportunity to qualify for the proposed higher maximum combined rebate and each of the proposed modified Liquidity Provision Tiers 1 and 2, the Liquidity Removal Tier, the Non-Display Add Tier 1, the NBBO Setter Tier 1, Cross-Asset Tier 2, and DLI Additive Rebate would be available to all Members that meet the associated volume requirements in any month. For the foregoing reasons, the Exchange believes the proposed changes would not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intermarket Competition

As noted above, the Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. Members have numerous alternative venues that they may participate on and direct their order flow to, including 15 other equities exchanges and numerous alternative trading systems and other off-exchange venues. As noted above, no single registered equities exchange currently has more than approximately 16% of the total market share of executed volume of equities trading. Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant

[25] 15 U.S.C. 78f(b)(4) and (5).

[26] *See supra* note 24.

pricing power in the execution of order flow. Moreover, the Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue to reduce use of certain categories of products, in response to new or different pricing structures being introduced into the market. Accordingly, competitive forces constrain the Exchange's transaction fees and rebates and market participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. As described above, the proposed changes represent a competitive proposal through which the Exchange is seeking to generate additional revenue with respect to its transaction pricing and to encourage the submission of additional order flow to the Exchange through volume-based tiers, which have been widely adopted by exchanges, including the Exchange. Accordingly, the Exchange believes the proposal would not burden, but rather promote, intermarket competition by enabling it to better compete with other exchanges that offer similar pricing incentives to market participants.

Additionally, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [27] The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition* v. *SEC,* the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .''.[28] Accordingly, the Exchange does not believe its proposed pricing changes impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act [29] and Rule 19b–4(f)(2) [30] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–MEMX–2024–16 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–MEMX–2024–16. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–MEMX–2024–16 and should be submitted on or before June 7, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–10821 Filed 5–16–24; 8:45 am]

BILLING CODE 8011–01–P

[27] *Id.*

[28] *NetCoalition* v. *SEC,* 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSE–2006–21)).

[29] 15 U.S.C. 78s(b)(3)(A)(ii).

[30] 17 CFR 240.19b–4(f)(2).

[31] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice: 12409]

Proposed Establishment of Federally Funded Research and Development Centers—First Notice

SUMMARY: The United States Department of State (DoS), Bureau of Administration, intends to sponsor Federally Funded Research and Development Centers (FFRDC) to facilitate public-private collaboration for numerous activities related to diplomacy and modernization. This is the first of three notices which must be published over a 90-day period in order to advise the public of the agency's intention to sponsor an FFRDC.

DATES: Written comments must be received by 5 p.m. eastern time on August 15, 2024.

ADDRESSES: Please send any comments by email to Jessalyn Lord at *LordJM@state.gov*.

FOR FURTHER INFORMATION CONTACT: Jessalyn Lord, *LordJM@state.gov* at 771–204–1366.

SUPPLEMENTARY INFORMATION: The Department of State leads U.S. engagement around the world building alliances and partnerships; facing up to aggression; aiding and supporting emerging democracies; and preserving U.S. interests abroad. In a rapidly changing world with shifting politics, accelerated economic developments, global challenges such as climate change, and the increasing role digitization plays for both opportunity and threats, the Department is committed to leading through both policy and operational engagement on behalf of the Nation and our Government.

In a letter introducing the Department of State and U.S. Agency for International Development Joint Strategic Plan for 2022–2026, Secretary Blinken stated, ''we are working to modernize and equip the Department and USAID to lead on 21st-Century challenges and deliver for the American people.''

Achieving U.S. goals for global leadership over the next decade will require the following:

- A diplomatic corps to use data in new ways to develop more foresight and insight, to inform policy options, to take actions and measure their effectiveness;
- New cross-sector partnerships and coalitions;
- Intergovernmental partnerships with the Department of Defense, the intelligence agencies, the Departments of Commerce, Treasury, Homeland Security, and Health and Human Services, and cross-government Councils (*e.g.,* National Economic Council, National Security Council);
- New capabilities to plan, manage and execute initiatives and programs;
- A workforce that uses digital technology as tools to advance democracy and protect our interests and counter the use of these same technologies as a threat; and
- An organization and operation that is agile and adaptive to a changing environment; attractive to new talent; and fosters long-term commitment between the organization and its people.

The Department requires long-term partnerships with organizations that can bring research, development, innovation, and support needed to guide the leadership and employees through this transformative period in our history. This will allow the Department to focus on the mission at hand, while adopting and integrating changes necessary to make consistent progress on these goals and surge, when needed, to address urgent issues that require data, partnerships, technology and insights applied in near-term operational situations.

To meet this need, the Department seeks to establish and sponsor three (3) FFRDCs. The FFRDCs will be established under the authority of 48 CFR 35.017.

The FFRDCs will be available to provide a wide range of support including, but not limited to the activities listed below. The FFRDCs will be separated into 3 areas:

Operational Support

○ Acquisition Planning and Development

▪ Developing comprehensive acquisition policies and implementation guidance that promote innovation by integrating new technologies, methodologies, and best practices to enhance efficiency and outcomes.

▪ Developing and implementing integrated frameworks that synchronize the acquisition priorities and budgeting lifecycle using advanced data driven methodologies to ensure that acquisition strategies and resource allocation align with strategic objectives.

▪ Executing detailed assessments to analyze and document acquisition requirements, facilitating joint requirements through collaborative tools, and developing detailed requirements through alternative solution analysis, trade-off studies and formal validation processes.

▪ Providing technical expertise and reviewing critical acquisition documents.

▪ Advising on the cost, schedule, and performance aspects of the acquisition program.

○ Operational Analysis and Organizational Innovation

▪ Designing, developing, and executing comprehensive assessments to map existing operational capabilities, identify gaps, and develop actionable plans to bridge the gap between current and desired capabilities, including recommendations for resource allocation, training, and technological upgrades.

▪ Designing, developing and establishing innovative organizational structures and business models that can better support strategic and operational goals using best practices from both public and private sectors to drive innovation.

▪ Providing expert guidance on implementing strategic plans and Key Performance Indicator systems, including scenario planning and the use of contingency strategies to handle potential future challenges.

▪ Designing, evaluating, and refining human resources management frameworks to align with Federal regulations, improve organizational culture, and integrate best practices in workforce analytics.

Emerging Threats, Concept Exploration, Experimentation and Evaluation

○ Developing concepts, models, simulations (for purposes of conceptual experimentation and evaluation, not for operational training), tools and metrics to evaluate system tradeoffs, integration strategies, and support critical decision making.

○ Applying statistical analysis and evaluation techniques.

○ Developing prototypes and proof-of-concept demonstrations.

○ Designing, developing and establishing unique test-beds, laboratories, and other experimentation environments.

○ Evaluating of alternative technologies and capabilities.

Information Technology (IT) and Cyber Operations

○ IT and Communications

▪ Developing and evaluating—

(i) Data processing methodologies including data transmission, storage, retrieval and manipulation

(ii) Computational algorithms, search engine technologies, semantical relationships and non-structured data analytics

(iii) Networking, telecommunications and communications technology

(iv) Computer technologies, cloud services and enterprise applications resource planning

▪ Cyber Operations, Assessment, and Solutions

▪ Leveraging big data analytics and using machine learning to develop comprehensive threat intelligence capabilities that aggregate and analyze threat data from multiple sources to enable the identification of emerging threats and vulnerabilities, facilitating timely and informed decision-making.

▪ Developing of continuous monitoring systems that provide real-time visibility into networks and devices and utilize advanced forensic tools to conduct in-depth investigations into incidents.

▪ Development of data security and risk assessment protocols to safeguard Federal data within Federal systems and in external environments where Federal data is process or stored.

○ Systems Engineering, System Architecture and Integration

- Developing and reviewing systems design optimization and trade-space considerations.
- Designing and developing of integrating architectures and frameworks for existing and emerging systems and applications.
- Applying enterprise systems engineering principles to overall systems integration and aggregation considerations.

The FFRDCs will partner with the Department of State in the design and pursuit of mission goals; provide rapid responsiveness to changing requirements for personnel in all aspects of strategic, technical and program management; recognize Government objectives as its own objectives, partner in pursuit of excellence in public service; and allow for use of the FFRDC by non-sponsors.

The Department is publishing this notice in accordance with 48 CFR 5.205(b) of the Federal Acquisition Regulations (FAR) to enable interested members of the public to provide comments on this proposed action. This is the first of three notices issued under the authority of 48 CFR 5.205(b).

In particular, we are interested in feedback regarding the proposed scope of the work to be performed by the FFRDCs, and the presence of any existing private- or public-sector capabilities in these areas that the Department should be considering.

It is anticipated that the corresponding Request(s) for Proposal (RFP) will be posted on *sam.gov* in the Summer of 2024.

Alternatively, a copy of the RFP can be obtained by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section above once the RFP is posted.

Michael W. Derrios,

Deputy Assistant Secretary for Acquisition, & Senior Procurement Executive, U.S. Department of State.

[FR Doc. 2024–10842 Filed 5–16–24; 8:45 am]

BILLING CODE 4710–24–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Submission Deadline for Schedule Information for Chicago O'Hare International Airport, John F. Kennedy International Airport, Los Angeles International Airport, Newark Liberty International Airport, and San Francisco International Airport for the Winter 2024/25 Scheduling Season

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

ACTION: Notice of submission deadline.

SUMMARY: Under this notice, the FAA announces the submission deadline of May 17, 2024, for Winter 2024/25 flight schedules at Chicago O'Hare International Airport (ORD), John F. Kennedy International Airport (JFK), Los Angeles International Airport (LAX), Newark Liberty International Airport (EWR), and San Francisco International Airport (SFO).

DATES: Schedules should be submitted by May 17, 2024.

ADDRESSES: Schedules may be submitted to the Slot Administration Office by email to: *7-AWA-slotadmin@faa.gov*.

FOR FURTHER INFORMATION CONTACT: Al Meilus, Manager, Slot Administration and Capacity Analysis, AJR–G, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267–2822; email *Al.Meilus@faa.gov*.

SUPPLEMENTARY INFORMATION: This document provides routine notice to carriers serving capacity-constrained airports in the United States, including ORD, JFK, LAX, EWR, and SFO. In particular, this notice announces the deadline for carriers to submit schedules for the Winter 2024/2025 scheduling season.

General Information for All Airports

The FAA has designated JFK as an IATA Level 3 airport consistent with the Worldwide Slot Guidelines (WSG).[1] The FAA currently limits scheduled operations at JFK by order that expires on October 24, 2026.[2]

The FAA has designated EWR, LAX, ORD, and SFO as IATA Level 2 airports[3] subject to a schedule review process premised upon voluntary cooperation. The Winter 2024/2025 scheduling season is from October 27, 2024, through March 29, 2025, in recognition of the IATA Winter scheduling period.

The FAA is primarily concerned about scheduled and other regularly conducted commercial operations during designated hours, but carriers may submit schedule plans for the entire day. The designated hours for the Winter 2024/2025 scheduling season are: at EWR and JFK from 0600 to 2300 Eastern Time (1000 to 0300 UTC), at LAX and SFO from 0600 to 2300 Pacific Time (1300 to 0600 UTC), and at ORD from 0600 to 2100 Central Time (1100 to 0200 UTC). These hours are unchanged from previous scheduling seasons.

Carriers should submit schedule information in sufficient detail including, at minimum, the marketing or operating carrier, flight number, scheduled time of operation, frequency, aircraft equipment, and effective dates. IATA standard schedule information format and data elements for communications at Level 2 and Level 3 airports in the IATA Standard Schedules Information Manual (SSIM) Chapter 6 may be used. The WSG provides additional information on schedule submissions at Level 2 and Level 3 airports. Some carriers at JFK manage and track slots through FAA-assigned Slot ID numbers corresponding to an arrival or departure slot in a particular half-hour on a particular day of week and date. The FAA has a similar voluntary process for tracking schedules at EWR with Reference IDs, and certain carriers are managing their schedules accordingly. The primary users of IDs are United States and Canadian carriers that have the highest frequencies and considerable schedule changes throughout the season and can benefit from a simplified exchange of information not dependent on full flight details. Carriers are encouraged to submit schedule requests at those airports using Slot or Reference IDs.

As stated in the WSG, schedule facilitation at a Level 2 airport is based on the following: (1) Schedule adjustments are mutually agreed upon between the carriers and the facilitator; (2) the intent is to avoid exceeding the airport's coordination parameters; (3) the concepts of historic precedence and series of slots do not apply at Level 2 airports, although WSG recommends giving priority to approved services that plan to operate unchanged from the previous equivalent season at Level 2 airports; and (4) the facilitator should adjust the smallest number of flights by the least amount of time necessary to avoid exceeding the airport's coordination parameters. Consistent with the WSG, the success of Level 2 in

[1] The FAA generally applies the WSG to the extent there is no conflict with U.S. law or regulation. The FAA recognizes the WSG has been replaced by the Worldwide Airports Slot Guidelines (WASG) edition 1, effective June 1, 2020, and subsequently WASG edition 2, effective July 1, 2022. The WASG is published jointly by Airports Council International-World, IATA, and the Worldwide Airport Coordinators Group (WWACG). While the FAA is considering whether to implement certain changes to the Guidelines in the United States, it will continue to apply WSG edition 9.

[2] Operating Limitations at John F. Kennedy International Airport, 73 FR 3510 (Jan. 18, 2008), as most recently extended 89 FR 41486 (May 13, 2024). The slot coordination parameters for JFK are set forth in this Order.

[3] These designations remain effective until the FAA announces a change in the **Federal Register**.

the United States depends on the voluntary cooperation of carriers.

The FAA considers several factors and priorities that are consistent with the WSG as it reviews schedule and slot requests at Level 2 and Level 3 airports, including (1) historic slots or services from the previous equivalent season over new demand for the same timings; (2) services that are unchanged over services that plan to change time or other capacity relevant parameters; (3) introduction of year-round services; (4) effective period of operation; (5) regularly planned operations over *ad hoc* operations; and (6) other operational factors that may limit a carrier's timing flexibility.

The FAA seeks to maintain close communications with carriers and terminal schedule facilitators on potential runway schedule issues or terminal and gate issues that may affect the runway times. In addition to applying these priorities from the WSG, the U.S. Government has adopted a number of measures and procedures to promote competition and new entry at U.S. slot-controlled and schedule-facilitated airports.

Slot management in the United States differs in some respect from procedures in other countries. In the United States, the FAA is responsible for facilitation and coordination of runway access for takeoffs and landings at Level 2 and Level 3 airports; however, the airport authority or its designee is responsible for facilitation and coordination of terminal/gate/airport facility access. The process with the individual airports for terminal access and other airport services is separate from, and in addition to, the FAA schedule review based on runway capacity.

Generally, the FAA uses average hourly runway capacity throughput for airports and performance metrics in conducting its schedule review at Level 2 airports and determining the scheduling limits at Level 3 airports included in FAA rules or orders.[4] The FAA also considers other factors that can affect operations, such as capacity changes due to runway, taxiway, or other airport construction, air traffic control procedural changes, airport surface operations, and historical or projected flight delays and congestion.

Finally, the FAA notes that the schedule information submitted by carriers to the FAA may be subject to disclosure under the Freedom of Information Act (FOIA). The WSG also provides for release of information at certain stages of slot coordination and schedule facilitation. In general, once it acts on a schedule submission or slot request, the FAA may release information on slot allocation or similar slot transactions, or schedule information reviewed as part of the schedule facilitation process. The FAA does not expect that practice to change, and most slot and schedule information would not be exempt from release under FOIA. The FAA recognizes that some carriers may submit information on schedule plans that is both customarily and actually treated as private. Carriers that submit such confidential schedule information should clearly mark the information, or any relevant portions thereof, as proprietary information (''PROPIN''). The FAA will take the necessary steps to protect properly designated information to the extent allowable by law.

EWR General Information

Consistent with the WSG, carriers are asked for their voluntary cooperation to adjust schedules to meet the targeted scheduling limits in order to minimize potential congestion and delay. For the Winter 2024/2025 scheduling season, the voluntary, targeted hourly scheduling limits remain at 77 operations and 41 operations per half-hour.[5] To help with a balance between arrivals and departures, the targeted maximum number of scheduled arrivals or departures, respectively, is 41 in an hour and 22 in a half-hour. These targets are expected to allow some higher levels of operations in certain periods (not to exceed the hourly limits) and some recovery from lower demand in adjacent periods. Consistent with general established practice at EWR, the FAA will accept flights above the limits if the flights were operated as approved, or treated as operated, by the same carrier on a regular basis in the previous corresponding season (*i.e.,* Winter 2023/2024) and consistent with DOT's 2022 reassignment of 16 peak-hour runway timings.[6] However, the FAA does not intend to approve requests for new flights unless they can be accommodated within the targeted limits. The FAA is seeking carriers' voluntary cooperation to get scheduled operations down to the targeted scheduling limits.

Carriers are reminded that FAA approval for runway times is separate from the approval process for gates or other airport infrastructure and both are essential for the success of Level 2 at EWR. Schedule facilitation at Level 2 airports is designed to engender collaboration and gain mutual agreement between the carriers and the FAA regarding schedules and potential adjustments to stay within the performance goals and capacity limits of the airport and to mitigate delays and congestion that would result in the need for Level 3 slot controls. The FAA expects that all carriers operating at EWR will respect the targeted scheduling limits and work cooperatively with the FAA in order to avoid unacceptable delays and other adverse operational impacts at the airport.

Issued in Washington, DC, on May 15, 2024.

Alyce Hood-Fleming,

Vice President, System Operations Services.

[FR Doc. 2024–11012 Filed 5–16–24; 4:15 pm]

BILLING CODE 4910–13–P

[4] The FAA typically determines an airport's average adjusted runway capacity or typical throughput for Level 2 airports by reviewing hourly data on the arrival and departure rates that air traffic control indicates could be accepted for that hour, commonly known as ''called'' rates. The FAA also reviews the actual number of arrivals and departures that operated in the same hour. Generally, the FAA uses the higher of the two numbers, called or actual, for identifying trends and schedule review purposes. Some dates are excluded from analysis, such as during periods when extended airport closures or construction could affect capacity.

[5] See 88 FR 64964 (September 20, 2023).

[6] See Department of Transportation Order 2022–7–1, Docket DOT–OST–2021–0103, served July 5, 2022, ''Reassignment of Schedules at Newark-Liberty International Airport.''

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Transportation Project in Florida

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of limitation on claims for judicial review of actions by Florida Department of Transportation (FDOT) and other Federal agencies.

SUMMARY: The FHWA, on behalf of the FDOT, is issuing this notice to announce actions taken by FDOT and other Federal agencies that are final agency actions. These actions relate to the proposed Interstate 75 (I–75) Improvements Project Development and Environment (PD&E) Study (Financial Management Number 452074–1). The proposed I–75 Improvements project will reduce congestion and improve reliability on I–75 from S.R. 200 to S.R. 326, a distance of approximately 8 miles. Improvements consist of adding auxiliary lanes between interchanges, bridge overpass replacement and widening, and the construction of stormwater management facilities.

These actions grant licenses, permits, or approvals for the project.

DATES: By this notice, the FHWA, on behalf of FDOT, is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency actions on the listed highway project will be barred unless the claim is filed on or before October 15, 2024. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

ADDRESSES: The Type 2 Categorical Exclusion and additional project documents can be viewed and downloaded from the project website at: *https://www.cflroads.com/project/452074-1,* or by contacting FDOT Office of Environmental Management, 605 Suwannee Street, MS 37, Tallahassee, Florida 32399, during normal business hours are 8:00 a.m. to 5:00 p.m. (Eastern Standard Time), Monday through Friday, except State holidays.

FOR FURTHER INFORMATION CONTACT: Jennifer Marshall, P.E., Director, FDOT Office of Environmental Management, FDOT; telephone (850) 414–4316; email: *Jennifer.Marshall@dot.state.fl.us.*

SUPPLEMENTARY INFORMATION: Effective December 14, 2016, and as subsequently renewed on May 26, 2022, the FHWA assigned, and the FDOT assumed, environmental responsibilities for this project pursuant to 23 U.S.C. 327. Notice is hereby given that FDOT and other Federal agencies have taken final agency actions subject to 23 U.S.C. 139(l)(1) by issuing licenses, permits, or approvals for the proposed highway improvement project. The actions by FDOT and other Federal agencies on the project, and the laws under which such actions were taken are described in the Type II Categorical Exclusion approved on April 19, 2024, and in other project records for the listed project. The Type II Categorical Exclusion and other documents for the listed project are available by contacting FDOT at the address provided above. The project subject to this notice is:

Project Location: The project is located in Marion County, Florida, and partially within the City of Ocala. The project limits are I–75 from S.R. 200 to S.R. 326, a distance of approximately 8 miles.

Project Actions: This notice applies to the Type II Categorical Exclusion and all other Federal agency licenses, permits, or approvals for the listed project as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321*et seq.*]; Federal-Aid Highway Act (FAHA) [23 U.S.C. 109 and 23 U.S.C. 128]; 23 CFR part 771.

2. *Air:* Clean Air Act (CAA) [42 U.S.C. 7401–7671(q)], with the exception of project level conformity determinations [42 U.S.C. 7506].

3. *Noise:* Noise Control Act of 1972 [42 U.S.C. 4901–4918]; 23 CFR part 772.

4. *Land:* Section 4(f) of the Department of Transportation Act of 1966 [23 U.S.C. 138 and 49 U.S.C. 303]; 23 CFR part 774; Land and Water Conservation Fund (LWCF) [54 U.S.C. 200302–200310].

5. *Wildlife:* Endangered Species Act (ESA) [16 U.S.C. 1531–1544 and 1536]; Marine Mammal Protection Act [16 U.S.C. 1361–1423h], Anadromous Fish Conservation Act [16 U.S.C. 757(a)–757(f)]; Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)]; Migratory Bird Treaty Act (MBTA) [16 U.S.C. 703–712]; Magnuson-Stevenson Fishery Conservation and Management Act of 1976, as amended [16 U.S.C. 1801–1891d], with Essential Fish Habitat requirements [16 U.S.C. 1855(b)(2)].

6. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [54 U.S.C. 3006101 *et seq.*]; Archaeological Resources Protection Act of 1979 (ARPA) [16 U.S.C. 470(aa)–470(II)]; Preservation of Historical and Archaeological Data [54 U.S.C.312501–312508]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013; 18 U.S.C. 1170] .

7. *Social and Economic:* Civil Rights Act of 1964 [42 U.S.C. 2000 d–2000d–1]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

8. *Wetlands and Water Resources:* Clean Water Act (section 319, section 401, section 404) [33 U.S.C. 1251–1387]; Coastal Barriers Resources Act (CBRA) [16 U.S.C. 3501–3510]; Coastal Zone Management Act (CZMA) [16 U.S.C. 1451–1466]; Safe Drinking Water Act (SDWA) [42 U.S.C. 300f–300j–26]; Rivers and Harbors Act of 1899 [33 U.S.C. 401–406]; Wild and Scenic Rivers Act [16 U.S.C. 1271–1287]; Emergency Wetlands Resources Act [16 U.S.C. 3921, 3931]; Wetlands Mitigation, [23 U.S.C. 119(g) and 133(b)(3)]; Flood Disaster Protection Act [42 U.S.C. 4001–4130].

9. *Hazardous Materials:* Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) [42 U.S.C. 9601–9675]; Superfund Amendments and Reauthorization Act of 1986 (SARA); Resource Conservation and Recovery Act (RCRA) [42 U.S.C. 6901–6992(k)].

10. *Executive Orders:* E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(l)(1).

Issued on: May 13, 2024.

Karen M. Brunelle,

Director, Office of Project Development, Federal Highway Administration, Tallahassee, Florida.

[FR Doc. 2024–10847 Filed 5–16–24; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2024–0092]

Commercial Learner's Permit (CLP): Connell High School; Application for Exemption

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of application for exemption; request for comments.

SUMMARY: FMCSA announces that Connell High School (CHS) of Connell, WA, has applied for an exemption beginning September 2024 to allow students under the age of 18 who are enrolled in CHS's Commercial Driver's License (CDL) Program to obtain a Commercial Learner's Permit (CLP). Students participating in the program would obtain a CLP at the age of 17 and receive 180 hours of classroom, field, and drive time instruction before obtaining a CDL at the age of 18. FMCSA requests public comment on the applicant's request for exemption.

DATES: Comments must be received on or before June 17, 2024.

ADDRESSES: You may submit comments identified by Federal Docket

Management System (FDMS) Number FMCSA–2024–0092 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, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building, Ground Floor, 1200 New Jersey Avenue SE, Washington, DC, 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–2024–0092) 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: If you do not have access to the internet, you may view the docket by visiting Docket Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, 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, 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.* The comments are posted without edit and are searchable by the name of the submitter.

FOR FURTHER INFORMATION CONTACT: Ms. Bernadette Walker, Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards, FMCSA; (202) 385–2415; *Bernadette.walker@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–2022–0122), indicate the specific section of this document to which the comment applies, and provide a reason for your 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–2024–0092'' in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, click the ''Comment'' button, and type your comment into the text box on 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.

Confidential Business Information (CBI)

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to the notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to the notice, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission that constitutes CBI as ''PROPIN'' to indicate it contains proprietary information. FMCSA will treat such marked submissions as confidential under the Freedom of Information Act, and they will not be placed in the public docket of the notice. Submissions containing CBI should be sent to Brian Dahlin, Chief, Regulatory Evaluation Division, Office of Policy, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001 or via email at *brian.g.dahlin@dot.gov.* At this time, you need not send a duplicate hardcopy of your electronic CBI submissions to FMCSA headquarters. Any comments FMCSA receives not specifically designated as CBI will be placed in the public docket for this notice.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including the applicant's safety analyses. The Agency must provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted and determines whether granting the exemption would likely maintain a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305(a)). The Agency must publish its decision in the **Federal Register** (49 CFR 381.315(b)). If granted, the notice will identify the regulatory provision(s) from which the applicant will be exempt, the effective period, and all terms and conditions of the exemption (49 CFR 381.315(c)(1)). If the exemption is denied, the notice will explain the reasons for the denial (49 CFR 381.315(c)(2)).

III. Applicant's Request

CHS seeks an exemption from 49 CFR 383.25(a)(4), which requires a CLP holder to be 18 years of age or older. CHS explains that it is a public high school located in Connell, WA, serving over 600 students in the 9th through 12th grades. CHS further states that its enrollment is 70% minority and 70% economically disadvantaged students. According to CHS, the school district serves a primarily agricultural community across four small rural towns, with a decreasing workforce but with an increasing agriculture and transportation demand.

CHS believes that granting the exemption will allow students to obtain a CDL at 18 years of age and, upon graduation from CHS, immediately enter the local workforce with stable, well-paying employment. CHS also believes that the exemption could have a positive impact on the local communities and alleviate the current commercial driver shortage. The applicant states that a similar program exists in the state of Maine and is

offered by public institutions and allows students as young as 16 years of age to obtain a CLP. CHS believes its robust CDL preparatory program will ensure CHS achieves a level of safety that is equivalent to, or greater than, the level of safety that would be obtained by complying with the regulation.

The applicant further states that, if granted, the exemption would allow students participating in the CHS CDL Training Program to obtain a CLP at the age of 17 and allow the program to span two semesters (one full school year) and provide 180 hours of classroom, field, and drive time instruction. CHS requests a five-year exemption.

A copy of the CHS's application for exemption is available for review in the docket for this notice.

IV. Request for Comments

In accordance with 49 U.S.C. 31315(b), FMCSA requests public comment from all interested persons on CHS's request for an exemption to change the CLP age requirement from 18 years of age to 17 years of age for CHS students enrolled in its CDL program, beginning in September 2024. 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.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2024–10856 Filed 5–16–24; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–NHTSA–2023–0062]

Agency Information Collection Activities; Notice and Request for Comment; National Traffic Safety Survey

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for comments on a request for approval of a new information collection.

SUMMARY: The National Highway Traffic Safety Administration (NHTSA) invites public comments about our intention to request approval from the Office of Management and Budget (OMB) for a new information collection. Before a Federal agency can collect certain information from the public, it must receive approval from OMB. Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatement of previously approved collections. This document describes six collections of information for which NHTSA intends to seek OMB approval that would be conducted as part of the National Traffic Safety Survey.

DATES: Comments must be submitted on or before July 16, 2024.

ADDRESSES: You may submit comments identified by the Docket No. NHTSA–2023–0062 through any of the following methods:

- *Electronic submissions:* Go to the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail or Hand Delivery:* Docket Management, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays. To be sure someone is there to help you, please call (202) 366–9322 before coming.

Instructions: All submissions must include the agency name and docket number for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *https://www.transportation.gov/privacy.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or the street address listed above. Follow the online instructions for accessing the dockets via internet.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact Christine Watson, Ph.D., Office of Behavioral Safety Research (NPD–320), 202–366–7345, *Christine.Watson@dot.gov,* National Highway Traffic Safety Administration, W46–474, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), before an agency submits a proposed collection of information to OMB for approval, it must first publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulation (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) how to enhance the quality, utility, and clarity of the information to be collected; and (d) how to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. In compliance with these requirements, NHTSA asks for public comments on the following proposed collection of information for which the agency is seeking approval from OMB.

Title: National Traffic Safety Survey.

OMB Control Number: New.

Form Numbers: NHTSA Forms #1805, 1805–S, 1806, 1806–S, 1807, 1807–S, 1808, 1808–S, 1809, 1809–S, 1810, 1810–S.

Type of Request: Request for 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:

The National Highway Traffic Safety Administration (NHTSA) proposes to collect information from the public to better understand the public's behavior and attitudes regarding traffic safety issues including seat belts, distracted driving, new and emerging vehicle technologies, and traffic safety and enforcement. Data would be collected by web and mail among a national probability sample of approximately 6,001 adults aged 18 and older per survey administration. NHTSA is proposing to conduct the full survey twice, two years apart, and conduct a pilot survey involving 250 individuals that would occur before the first full administration of the survey. Participation by respondents would be voluntary. Survey topics include key driving behaviors and experiences, behaviors, attitudes, and knowledge around seat belt use, distracted driving, new vehicle technologies, traffic safety, and traffic safety enforcement.

As part of the NTSS, NHTSA will send out six different version of the survey. Each of the surveys will contain a set of core questions that will be asked across all surveys and a combination of two additional sections consisting of questions related to seat belts, distracted driving, new vehicle technologies, or traffic safety and traffic safety enforcement. Based on the target of collecting 6,001 completed surveys, NHTSA estimates that the full administration of the survey will include approximately 1,000 completed surveys for each of the six versions.

In conducting the proposed research, the survey would use computer-assisted web interviewing (*i.e.,* a programmed, self-administered web survey) to minimize recording errors, as well as optical mark recognition and image scanning for the paper and pencil survey to facilitate ease of use and data accuracy. A Spanish-language survey option would be used to minimize language barriers to participation. Surveys would be conducted with respondents using an address-based sampling design that encourages respondents to complete the survey online. Although web would be the primary data collection mode, a paper questionnaire would be sent to households that do not respond to the web invitations. Any Personally Identifiable Information (PII) would be removed as only a de-identified dataset will be delivered to NHTSA. This collection only requires respondents to report their answers; there are no record-keeping costs to the respondents. Individuals receiving a survey invitation will receive compensation in return for their activities.

Description of the Need for the Information and Proposed Use of the Information:

NHTSA was established to reduce the number of deaths, injuries, and economic losses resulting from motor vehicle crashes on the Nation's highways. As part of this statutory mandate, NHTSA is authorized to conduct research as a foundation for the development of traffic safety programs. Title 23, United States Code, section 403 authorizes the Secretary of Transportation (NHTSA by delegation) 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.

A primary way NHTSA identifies problems and supports the development of effective countermeasures is through conducting nationally representative surveys of public attitudes, knowledge, and self-reported behaviors regarding various traffic safety topics. NHTSA has conducted seven previous iterations of the Motor Vehicle Occupant Safety Survey (MVOSS) to ascertain critical information on driver and passenger attitudes and behaviors related to safety; the MVOSS was most recently administered in 2016.[1] However, recent advances in vehicle safety technologies, increases in portable electronic device use, and changes in attitudes towards enforcement have all changed the driving environment, and there is a need to collect up-to-date information about the public's attitudes and behavior on these traffic safety topics to better inform programs aimed at improving the safety of all road users. The NTSS is the ''next generation'' of NHTSA's previous MVOSS, expanded across more traffic safety topics to increase relevance to current and future traffic safety issues. NTSS will deliver highly relevant, actionable data on current and future topics in traffic safety that support the agency's mission to save lives, prevent injuries, and reduce economic costs resulting from traffic crashes.

[1] Bailly, K., Martin, K. & Block, A. (2019, December). *2016 Motor vehicle occupant safety survey: Volume 1, Methodology report* (Report No. DOT HS 812 851). National Highway Traffic Safety Administration. *https://rosap.ntl.bts.gov/view/dot/43610.*

NHTSA will use the information collected from the NTSS to produce a technical report that presents the results of the survey, as well as a publicly available dataset that does not contain any PII. 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 PII. The technical report will be shared with State highway safety offices, local governments, policymakers, researchers, educators, advocates, and others who may use the data from this survey to support their work.

Affected Public: Participants will be English- and Spanish-speaking U.S. adults (18 years old and older).

Estimated Number of Respondents: Participation in this study will be voluntary, with 6,001 participants sampled from all 50 States and the District of Columbia using address data from the most recent U.S. Postal Service (USPS) computerized Delivery Sequence File (DSF) of residential addresses. An estimated 28,700 households will be contacted and invited to participate. No more than one respondent will be selected per household. Prior to the main survey, a pilot survey will be administered to test the survey and the mailing protocol and procedures. Participation in the pilot study will be voluntary, with approximately 250 participants sampled from all 50 States and the District of Columbia using address data from the most recent USPS computerized DSF of residential addresses. An estimated 1,200 households will be contacted and invited to participate in the pilot study. No more than one respondent will be selected per household.

Frequency: The study will be conducted up to two times during the three-year period for which NHTSA is requesting approval, with a small pilot study occurring several months before the study's full launch.

Estimated Total Annual Burden Hours:

To estimate the annul burden of the information collection request, NHTSA first estimated the total number of respondents that would complete each of the six surveys over the course of the three-year period for which NHTSA is seeking approval. Assuming that there will be 250 respondents to the pilot survey and 6,001 respondents in each of the two full administrations of the survey, NHTSA estimates a total of 12,250 respondents in the three-year period, or approximately 4,084 per year. With this estimate, NHTSA estimates that, on average, approximately 681

respondents will complete each of the six surveys annually.

The first survey administration will be a pilot survey will assess the entire survey administration system prior to launching the full survey and will include an experimental condition examining the effectiveness of different messaging techniques used in contact materials to increase survey response rates. The pilot administration will survey approximately 250 randomly selected respondents. This will be followed by a first administration of the survey with approximately 6,001 randomly selected respondents during the main data collection effort. NHTSA may exercise an option to survey approximately 6,001 randomly selected respondents during a second survey administration. For purposes of this information collection request, NHTSA assumes that it will conduct the second administration.

For the pilot survey, a mass mailing using USPS DSF to 1,200 addresses, of which 1,140 are expected to be valid contact addresses, is expected to reach about 250 willing respondents ages 18 and older. Respondents are expected to take 30 minutes to complete the survey (250 people, 30 minutes average length, 125 hours total).

For each survey administration, a mass mailing using USPS DSF to 28,700 addresses, of which 27,265 are expected to be valid contact addresses, is expected to reach about 6,001 willing participants ages 18 and older. As with the pilot survey, participants are expected to take 30 minutes to complete the survey.

Table 1 provides an overview of the survey administrations.

TABLE 1—OVERVIEW OF THE SURVEY ADMINISTRATIONS

Information collection	Number of respondents	Burden per response (minutes)	Total burden hours
Pilot Survey	250	30	125
Survey Administration 1	6,001	30	3,001
Survey Administration 2	6,001	30	3,001
Total	12,252	.....	6,127

Since the survey administrations would occur over three years, NHTSA averaged the number of respondents responding to each of the six surveys over the three-year period to estimate that each of the surveys would have approximately 681 respondents per year. The burden estimates are based on this estimate.

NHTSA estimates that each of the six versions of the survey will have approximately 681 respondents each year and estimates that it takes approximately 30 minutes to complete each survey. Accordingly, NHTSA estimates that each of the surveys will have a burden of 341 hours per year, for a total of 2,046 hours of annual burden for all six of the surveys.

NHTSA estimates the opportunity cost to respondents using an average hourly wage. The May 2022 mean hourly wage for all occupations in the United States was $29.76 per hour.[2] Therefore, NHTSA estimates the total annual opportunity cost to be approximately $60,889 ($29.76 × 2,046 = $60,888.96). Table 2 provides a summary of the estimated annual burden hours and labor costs associated with those submissions.

TABLE 2—ANNUAL BURDEN ESTIMATES

Information collection	Number of respondents	Burden per response (minutes)	Hourly opportunity cost	Opportunity cost response	Total opportunity cost	Total burden hours
Survey Version 1	681	30	$29.76	$14.88	$10,148.16	341
Survey Version 2	681	30	29.76	14.88	10,148.16	341
Survey Version 3	681	30	29.76	14.88	10,148.16	341
Survey Version 4	681	30	29.76	14.88	10,148.16	341
Survey Version 5	681	30	29.76	14.88	10,148.16	341
Survey Version 6	681	30	29.76	14.88	10,148.16	341
Total	.....	.....	.....	.....	60,888.96	2,046

Estimated Total Annual Burden Cost: Participation in this study is voluntary, and there are no costs to respondents beyond the time spent completing the questionnaires.

Public Comments Invited: You are asked to comment on any aspects of this information collection, including (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the Department's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as

[2] U.S. Bureau of Labor Statistics. (2023, April 25). *May 2022 National Occupational Employment and Wage Estimates.* U.S. Bureau of Labor Statistics. *https://www.bls.gov/oes/current/oes_nat.htm#00-0000.*

amended; 49 CFR 1.49; and DOT Order 1351.29A.

Nanda Narayanan Srinivasan,

Associate Administrator, Research and Program Development.

[FR Doc. 2024–10851 Filed 5–16–24; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No.: DOT–OST–2023–0136]

Privacy Act of 1974; System of Records

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of a new system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Transportation (DOT) proposes a new system of records titled ''DOT/FMCSA 014 Electronic Logging Device (ELD) Records''. This system of records is used to facilitate the retrieval, transfer, and collection of hours-of-service (HOS) data from electronic ELD files submitted by motor carriers and the review of HOS data by authorized safety officials. The system retrieves data recorded by a motor carrier's ELD via an ELD output file. Upon receipt of this ELD output file, the system analyzes the data, identifies instances of potential non-compliance, and notifies the authorized safety official of these instances. FMCSA maintains ELD data for use in investigations and enforcement actions and to determine compliance with HOS requirements. The primary purpose of the ELD system is to allow authorized safety officials to assess electronic ELD files rapidly and accurately at roadside and during reviews and safety audits to determine whether the driver is in compliance with the HOS regulations. The ELD system will also be used to assess whether ELDs meet certain technical specifications that are set forth in the HOS regulations. Additionally, the Agency may use ELD data internally to inform research efforts related to enforcement of safety regulations, including driving hours, as such research may ultimately improve compliance with HOS requirements.

DATES: Comments on the system will be accepted on or before 30 days from the date of publication of this notice. The system will be effective 30 days after publication of this notice. Routine uses will be effective at that time.

ADDRESSES: You may submit comments, identified by docket number OST-2023–0136 by one of the following methods:

- *Federal e-Rulemaking Portal: https://www.regulations.gov.*
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. 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 Ave. SE, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

Instructions: You must include the agency name and docket number DOT–OST–2023–0136. All comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: For general and privacy questions, please contact: Karyn Gorman, Departmental Chief Privacy Officer, Department of Transportation, S–83, Washington, DC 20590, Email: *privacy@dot.gov,* Tel. (202) 366–3140.

SUPPLEMENTARY INFORMATION:

Background

In accordance with the Privacy Act of 1974, the Department of Transportation is proposing a new system of records titled ''Department of Transportation (DOT)/Federal Motor Carrier Safety Administration (FMCSA) 014, Electronic Logging Device Records.'' This system will access hours-of-service (HOS) data via electronic logging device (ELD) files submitted by motor carriers and will allow authorized safety officials to assess these electronic ELD files rapidly and accurately at roadside and during reviews and safety audits to determine whether the driver is in compliance with the HOS regulations. This system will also assess whether ELDs meet certain technical specifications that are set forth in HOS regulations and support removals from a list of self-certified devices. See 49 CFR part 395 subpart B, app. A. Additionally, the Agency may use data from this system internally and/or in aggregated and anonymized form to inform research efforts related to enforcement of safety regulations, including driving hours, as such research may ultimately improve compliance with HOS requirements. For example, the use of ELD data in research related to operational testing of electronic, in-motion commercial motor vehicle (CMV) inspections may increase roadside inspection capacity and further facilitate enforcement of HOS requirements.

Section 32301(b) of the Commercial Motor Vehicle Safety Enhancement Act of 2012 (enacted as part of the Moving Ahead for Progress in the 21st Century Act (MAP–21)) codified at 49 U.S.C. 31137, mandated that the Secretary of Transportation adopt regulations requiring that CMVs, operated in interstate commerce by drivers required to maintain records of duty status (RODS), be equipped with ELDs. The statute also set forth specific provisions to be addressed by the regulations, including ELD design and performance standards and certification requirements. In addition, the statute addresses privacy protections and the use of ELD data, requiring that the regulations ensure that ELDs are not used to harass a CMV operator. On December 16, 2015, FMCSA, acting primarily under the authority of MAP–21 (and several concurrent statutory authorities), published a final rule, Electronic Logging Devices and Hours of Service Supporting Documents (80 FR 78292) requiring the use of ELDs for recording HOS information. Under the regulations, which were implemented on December 18, 2017, CMVs operated in interstate commerce, by drivers required to maintain RODS, must be equipped with ELDs. The regulations also establish ELD performance and design standards, require ELDs to be certified and registered with FMCSA, and address privacy protections for CMV operators. The ELD regulations are set forth in 49 CFR part 395, subpart B.

FMCSA's ELD system consists of the following components:

- Electronic Record of Duty Status (eRODS) HOS review tool
- ELD website and database
- ELD provider web service
- Enforcement ELD web service
- Enforcement ELD summary data web service

Electronic Record of Duty Status (eRODS) HOS review tool. eRODS is a software application installed on authorized safety officials' computers that is used to retrieve and display the information on an ELD output file. eRODS allows enforcement users to analyze a driver's HOS data and perform a roadside inspection or an investigation. There is also a web-based version of eRODS that consists of all the functionality included in the desktop version but is accessible via the ELD website described below. ELD devices used by motor carriers are required to support one of two options for providing an ELD file to FMCSA for analysis via the eRODS HOS review tool:

Option 1 is the telematics transfer method. ELD devices that utilize the telematics transfer method support transfer of ELD files to the FMCSA's ELD system via web services transfer or encrypted email transfer. With the web service transfer method, the ELD device sends the ELD file directly to FMCSA servers via a secure call to the ELD provider web service, which makes the ELD file available to eRODS. For the email transfer, the ELD device sends the data file via secure, encrypted email to FMCSA servers which process the email and make the ELD file available to eRODS.

Option 2 is local transfer, which consists of Bluetooth connection or USB transfer. The Bluetooth connection allows the motor carrier's ELD to use the safety official's internet connection to transfer the ELD file to the ELD provider web service. The USB transfer method uses the safety official's self-encrypting USB device to transfer the ELD file from the motor carrier's ELD device to the safety official's eRODS application. This is the only method that does not require internet connectivity.

ELD website and database. The ELD website and database is the centerpiece of FMCSA's ELD system. The website includes a section for each stakeholder. ELD vendors use the website to register their organization with FMCSA and to self-certify their devices' compliance with ELD regulations. ELD vendors also have access to tools necessary to build and test their interfaces with FMCSA. Motor carriers and drivers can access the ELD website to obtain information on the ELD Rule and other communications that educate them on the ELD process. They can also review the list of self-certified ELD devices. Enforcement users can access ELD policy and training information related to ELDs and can access web eRODS to review motor carrier HOS compliance. The FMCSA vendor vetting team also reviews ELD vendor submissions for completeness.

ELD provider web service. The ELD provider web service provides the means for a registered, self-certified ELD device to transfer, via web service or blue-tooth transfer options, an ELD file to FMCSA. During the self-certification process for an ELD device, the ELD vendor provides FMCSA with their public certificate and receives FMCSA's public certificate and additional information on building the connection between their ELD and FMCSA's ELD provider web service. Once the connection is established, the ELD can submit output files of a driver's HOS data to FMCSA via this service.

Enforcement ELD web service. The enforcement ELD web service is used to transfer the ELD files submitted to FMCSA to the safety official's eRODS HOS review tool. Both the desktop and web-based eRODS tools connect to this service. Files that are submitted via ELD provider web service, Bluetooth connection, or email can be accessed by enforcement via a connection to this service.

Enforcement ELD summary data web service. This service provides safety officials summary information derived from the contents of an ELD file that was submitted to the ELD system. This summary data enables safety officials to review indicators prompting further analysis and also allows implementation of a direct link to eRODS tool for HOS analysis. FMCSA's ELD system of records will also serve as a central repository of ELD information.

FMCSA has also included DOT General Routine Uses, to the extent they are compatible with the purposes of this System. As recognized by the Office of Management and Budget (OMB) in its Privacy Act Implementation Guidance and Responsibilities (65 FR 19746 (July 9, 1975)), the routine uses include proper and necessary uses of information in the system, even if such uses occur infrequently. FMCSA has included in this notice routine uses for disclosures to law enforcement when the record, on its face, indicates a violation of law, to DOJ for litigation purposes, or when necessary to investigate or respond to a breach or potential breach of this system or other agencies' systems. DOT may disclose to Federal, State, local, or foreign agency information relevant to law enforcement, litigation, and proceedings before any court or adjudicative or administrative body. OMB has long recognized that these types of routine uses are ''proper and necessary'' uses of information and qualify as compatible with agency systems (65 FR 19476, April 11, 2000).

In addition, OMB Memorandum M–17–12, directed agencies to include routine uses that will permit sharing of information when needed to investigate, respond to, and mitigate a breach of a Federal information system. DOT also has included routine uses that permit sharing with the National Archives and Records Administration when necessary for an inspection, to any Federal Government agency engaged in audit or oversight related to this system, or when DOT determines that the disclosure will detect, prevent, or mitigate terrorism activity. These types of disclosures are necessary and proper uses of information in this system because they further DOT's obligation to fulfill its records management and program management responsibilities by facilitating accountability to agencies charged with oversight in these areas, and DOT's obligation under the Intelligence Reform and Terrorism Prevention Act of 2004, Public Law 108–456, and Executive Order 13388 (Oct. 25, 2005) to share information necessary and relevant to detect, prevent, disrupt, preempt, or mitigate the effects of terrorist activities against the territory, people, and interests of the United States.

Privacy Act

The Privacy Act (5 U.S.C. 552a) governs the means by which Federal Government agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. The Privacy Act extends rights and protections to individuals who are U.S. citizens and lawful permanent residents. Additionally, the Judicial Redress Act (JRA) provides a covered person with a statutory right to make requests for access and amendment to covered records, as defined by the JRA, along with judicial review for denials of such requests. In addition, the JRA prohibits disclosures of covered records, except as otherwise permitted by the Privacy Act.

Below is the description of the Electronic Logging Device System of Records. In accordance with *5 U.S.C. 552*a(r), DOT has provided a report of this system of records to the OMB and to Congress.

SYSTEM NAME AND NUMBER:

Department of Transportation (DOT)/ Federal Motor Carrier Safety Administration (FMCSA) 014 Electronic Logging Device (ELD) Records.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records are maintained in a FedRAMP-certified third-party cloud environment. The contracts are maintained by DOT at 1200 New Jersey Avenue SE, Washington, DC 20590.

SYSTEM MANAGER(S):

Division Chief, Enforcement Division, Office of Enforcement and Compliance, FMCSA, U.S. Department of

Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 32301(b) of the Commercial Motor Vehicle Safety Enhancement Act, enacted as part of the Moving Ahead for Progress in the 21st Century Act (Pub. L. 112–141, 126 Stat. 405, (July 6, 2012), codified at 49 U.S.C. 31137. (MAP–21); 49 CFR parts, 385, 386, 390, and 395.

PURPOSE(S) OF THE SYSTEM:

The purposes of the system are to (1) allow Federal and State law enforcement agencies to match an interstate CMV driver's name with his or her HOS record; (2) allow authorized safety officials to perform HOS compliance-assurance and enforcement functions for the purposes of using personal information to verify the time, date, and location for duty status changes of interstate CMV drivers to ensure that motor carriers and interstate drivers comply with applicable HOS regulations; (3) allow for assessment of particular ELD models and units to determine that they meet the technical specifications set forth in the HOS regulations; and (4) allow ELD data to inform research efforts related to safety regulations, including driving hours, to improve compliance with HOS requirements.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals within this system include commercial motor vehicle CMV drivers.

CATEGORIES OF RECORDS IN THE SYSTEM:

Categories of records in the system include the following information about CMV Drivers. Data elements marked with an asterisk ''*'' may be PII linked to ELD username or driver/co-driver name or license number.

- ELD username
- Driver's first name, last name
- Co-driver first name, last name (if there is a co-driver)
- Co-driver ELD username (if there is a co-driver)
- Driver's license number or commercial driver's license number
- State of license issuance*
- Duty status*
- Date and time of each change of duty status*
- Location of CMV when the CMV's engine is turned on and turned off, at each change of duty status, and at intervals of no more than 60 minutes when the CMV is in motion.*
- Starting time for each 24-hour period (*e.g.,* 12 midnight, 12 noon). This is a requirement for paper RODS and carries over to ELDs. The reason is that many elements of the HOS regulations are based on activities within 24-hour periods.*
- Hours in each duty status to 1-minute accuracy.*
- Special driving mode status (*e.g.,* personal conveyance, yard move).*
- Log of user activity (''user'' is generally the driver, but could be a technician test-driving the CMV or a yard-hotelier repositioning the CMV)*
- 17-digit vehicle identification number (VIN)*

RECORD SOURCE CATEGORIES:

CMV drivers and motor carrier submit records to assist authorized safety officials to determine if drivers comply with applicable HOS regulations.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b), all or a portion of the records or information contained in this system may be disclosed outside DOT as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

System Specific Routine Uses

1. To Motor Carrier Safety Assistance Program (MCSAP) State partner agencies for use during investigations, safety audits, and roadside inspections of motor carriers. This routine use enables the MCSAP agencies to review and analyze motor carrier and driver HOS practices and data to enforce the HOS regulations.

Department General Routine Uses

2. In the event that a system of records maintained by DOT to carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether Federal, State, local or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation, or order issued pursuant thereto.

3a. Routine Use for Disclosure for Use in Litigation. It shall be a routine use of the records in this system of records to disclose them to the Department of Justice or other Federal agency conducting litigation when—(a) DOT, or any agency thereof, or (b) Any employee of DOT or any agency thereof, in their official capacity, or (c) Any employee of DOT or any agency thereof, in their individual capacity where the Department of Justice has agreed to represent the employee, or (d) The United States or any agency thereof, where DOT determines that litigation is likely to affect the United States, is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice or other Federal agency conducting the litigation is deemed by DOT to be relevant and necessary in the litigation, provided, however, that in each case, DOT determines that disclosure of the records in the litigation is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

3b. Routine Use for Agency Disclosure in Other Proceedings. It shall be a routine use of records in this system to disclose them in proceedings before any court or adjudicative or administrative body before which DOT or any agency thereof, appears, when—(a) DOT, or any agency thereof, or (b) Any employee of DOT or any agency thereof in their official capacity, or (c) Any employee of DOT or any agency thereof in their individual capacity where DOT has agreed to represent the employee, or (d) The United States or any agency thereof, where DOT determines that the proceeding is likely to affect the United States, is a party to the proceeding or has an interest in such proceeding, and DOT determines that use of such records is relevant and necessary in the proceeding, provided, however, that in each case, DOT determines that disclosure of the records in the proceeding is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

4. Disclosure may be made to a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual. In such cases, however, the Congressional office does not have greater rights to records than the individual. Thus, the disclosure may be withheld from delivery to the individual where the file contains investigative or actual information or other materials which are being used, or are expected to be used, to support prosecution or fines against the individual for violations of a statute, or of regulations of the Department based on statutory authority. No such limitations apply to records requested for Congressional oversight or legislative purposes; release is authorized under 49 CFR 10.35(9).

5. One or more records from a system of records may be disclosed routinely to the National Archives and Records Administration (NARA) in records

management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

6. DOT may make available to another agency or instrumentality of any government jurisdiction, including State and local governments, listings of names from any system of records in DOT for use in law enforcement activities, either civil or criminal, or to expose fraudulent claims, regardless of the stated purpose for the collection of the information in the system of records. These enforcement activities are generally referred to as matching programs because two lists of names are checked for match using automated assistance. This routine use is advisory in nature and does not offer unrestricted access to systems of records for such law enforcement and related antifraud activities. Each request will be considered on the basis of its purpose, merits, cost effectiveness and alternatives using Instructions on reporting computer matching programs to the Office of Management and Budget, OMB, Congress, and the public, published by the Director, OMB, dated September 20, 1989.

7. DOT may disclose records from this system, as a routine use, to appropriate agencies, entities, and persons when (1) DOT suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; (2) DOT has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by DOT or another agency or entity) that rely upon the compromised information; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DOT's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

8. DOT may disclose records from this system, as a routine use, to the Office of Government Information Services for the purpose of (a) resolving disputes between FOIA requesters and Federal agencies and (b) reviewing agencies' policies, procedures, and compliance in order to recommend policy changes to Congress and the President.

9. DOT may disclose records from the system, as a routine use, to contractors and their agents, experts, consultants, and others performing or working on a contract, service, cooperative agreement, or other assignment for DOT, when necessary to accomplish an agency function related to this system of records.

10. DOT may disclose records from this system, as a routine use, to an agency, organization, or individual for the purpose of performing audit or oversight operations related to this system of records, but only such records as are necessary and relevant to the audit or oversight activity. This routine use does not apply to intra-agency sharing authorized under section (b)(1) of the Privacy Act.

11. DOT may disclose from this system, as a routine use, records consisting of, or relating to, terrorism information (6 U.S.C. 485(a)(5)), homeland security information (6 U.S.C. 482(f)(1)), or Law enforcement information (Guideline 2 Report attached to White House Memorandum, ''Information Sharing Environment'', November 22, 2006) to a Federal, State, local, Tribal, territorial, foreign government and/or multinational agency, either in response to its request or upon the initiative of the Component, for purposes of sharing such information as is necessary and relevant for the agencies to detect, prevent, disrupt, preempt, and mitigate the effects of terrorist activities against the territory, people, and interests of the United States of America, as contemplated by the Intelligence Reform and Terrorism Prevention Act of 2004 (Pub. L. 108–458) and Executive Order 13388 (October 25, 2005).

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records in this system are stored electronically on a contractor-maintained cloud storage service.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

ELD and driver records may be retrieved by the following data elements: ELD file submittal date; Carrier Name, Carrier USDOT Number; Driver First Name; Driver Last Name; Driver License State; Driver License Number; ELD File Comment. ELD vendor records may be retrieved by the following data elements: ELD vendor name, phone number, address, email, ELD device name, ELD Identifier, ELD registration ID. Records of a driver may be retrieved by the following data elements: driver name, license state, license number, motor carrier name, USDOT number, investigation code, and file submittal date.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Motor carriers must retain records for six months from date of receipt. In accordance with FMCSA's MCMIS record schedule Job Number N1–557–05–007, item 5a for MCMIS inputs, where the data will be deleted after the information is converted or copied to the MCMIS master data files, backed up, and verified.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records in this system are safeguarded in accordance with applicable rules and policies, including all applicable DOT automated systems security and access policies. Appropriate controls have been imposed to minimize the risk of compromising the information that is being stored and ensuring confidentiality of communications using tools such as encryption, authentication of sending parties, and compartmentalizing databases; and employing auditing software. ELD data is encrypted at rest and in transit. Access to records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions. All personnel with access to data are screened through background investigations commensurate with the level of access required to perform their duties.

RECORD ACCESS PROCEDURES:

Individuals seeking access to and notification of any record contained in this system of records, or seeking to contest its content, may submit a request to the System Manager in writing to the address provided under ''System Manager and Address.''

- When an individual is seeking records about himself or herself from this system of records or any other Departmental system of records, the request must conform with the Privacy Act regulations set forth in 49 CFR part 10. The individual must verify their identity by providing their full name, current address, and date and place of birth. The individual must sign the request, and the individual's signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. No specific form is required. In addition, the individual should:
- Explain why the individual believes the Department would possess information on him/her;
- Identify which component(s) of the Department the individual believes may have the information about them;
- Specify when the individual believes the records would have been created; and

• Provide any other information that will help the FOIA staff determine which DHS component agency may have responsive records.

If an individual seeks records pertaining to another living individual, the requesting individual must include a statement from the second individual certifying their agreement to the requested access. Without the above information, the Department may not be able to conduct an effective search, and the individual's request may be denied due to lack of specificity or lack of compliance with applicable regulations.

CONTESTING RECORD PROCEDURES:

FMCSA depends upon drivers and motor carriers to submit data as accurately as possible. The ELD drivers review their records of duty status daily and certify their correctness prior to submission to the motor carriers and FMCSA. If a driver notices that information is missing or contains errors, the driver would use the motor carrier's ELD device to make the necessary corrections or enter missing information.

After a driver submits his or her certified daily records to the motor carrier, the motor carrier reviews those records. If the carrier identifies additional errors, the carrier may request the driver to make additional edits. However, motor carriers or dispatchers that suggest a change to a drivers' HOS records following submission to the carrier are to have the driver confirm or reject, and then re-certify the accuracy of the record. All edits have to be annotated to document the reason for the change. This procedure is intended to protect the integrity of the ELD records and to prevent related instances of potential driver harassment.

In support of a roadside inspection, investigation, or safety audit, a motor carrier submits his or her certified daily records to safety officials for an HOS review, the safety official may cite a violation based on these records.

FMCSA has a redress process to challenge inspection, investigation, and safety audit data. The process, called DataQs, is accessible at *https://dataqs.fmcsa.dot.gov.* DataQs provides an electronic method for motor carriers and drivers to file concerns about information maintained in FMCSA systems (principally, roadside inspection results included in MCMIS). The DataQs system automatically forwards data concerns to the appropriate Federal or State office for processing and resolution. Any challenges to data provided by State agencies are resolved by the appropriate State agency. The system also allows filers to monitor the status of each filing.

Under the DataQs process, FMCSA cannot ''correct the information associated with the ELD records'' that are stored in the motor carrier's information systems. If an interstate CMV driver is incorrectly identified in an enforcement action, the DataQs system provides an avenue for a driver or motor carrier to request FMCSA to correct enforcement information that it may store in its own information systems.

Individuals seeking to contest the content of any record pertaining to themselves in this system may also contact the System Manager following the Privacy Act procedures in 49 CFR part 10, subpart E, Correction of Records. Written requests for correction must conform with the Privacy Act regulations set forth in 49 CFR part 10. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, you may obtain forms for this purpose from the FMCSA Freedom of Information Act Officer *https://www.fmcsa.dot.gov/foia/foia-requestsor foia2@dot.gov.*

NOTIFICATION PROCEDURES:

Individuals seeking to contest the content of any record pertaining to themselves in the system may contact the System Manager following the procedures described in ''Record Access Procedures'' above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

Issued in Washington, DC.

Karyn Gorman,

Departmental Chief Privacy Officer.

[FR Doc. 2024–10811 Filed 5–16–24; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Publication of the List of Services, Software, and Hardware Incident to Communications

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of a list of items determined to be incident to communications in the Iranian Transactions and Sanctions Regulations.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing a list of items that have been determined to be incident to communications and therefore authorized for export or reexport to Iran under a general license issued pursuant to the Iranian Transactions and Sanctions Regulations (ITSR). The list previously existed as an annex to ITSR General License D and its subsequent iterations, General License D–1 and General License D–2, all of which were previously made available on OFAC's website. Concurrent with publication of the list, OFAC is publishing an updated version of the list that, effective 30 days after publication, will restrict the computing power of certain items on the list.

DATES: This list is effective May 17, 2024.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The text of the List of Services, Software, and Hardware Incident to Communications is available on the Iran Sanctions page on OFAC's website, and additional information concerning OFAC is available on OFAC's website (*www.treasury.gov/ofac*).

Background

On May 30, 2013, OFAC, in consultation with the Departments of State and Commerce, issued General License (GL) D under the Regulations. GL D was made available on OFAC's website and in the **Federal Register** (78 FR 43278, July 19, 2013). GL D authorized the exportation or reexportation, directly or indirectly, from the United States or by U.S. persons, wherever located, to persons in Iran of additional services, software, and hardware incident to personal communications, including fee-based versions of the software and services authorized in § 560.540. GL D also contained an Annex that listed items authorized for export or reexport that had been determined to be incident to personal communications.

On February 7, 2014, OFAC issued GL D–1, which replaced and superseded GL D in its entirety. GL D–1 was made available on OFAC's website and in the **Federal Register** (79 FR 13736, March 11, 2014). GL D–1 clarified certain aspects of GL D and added certain new

authorizations relating to the provision to Iran and importation from Iran of certain hardware, software, and services incident to personal communications. GL D–1 made minor amendments to the Annex from GL D. On September 23, 2022, OFAC issued GL D–2, which replaced and superseded GL D–1 in its entirety. GL D–2 was made available on OFAC's website and in the **Federal Register** (87 FR 62003, October 13, 2022), and updated and clarified GL D–1 by, among other things: removing the ''personal'' qualifier from the authorization for software and services incident to ''personal communication'' and providing additional examples of certain modern types of software and services that are incident to the exchange of communications.

OFAC is now publishing the list of items previously included in the annexes to GL D, GL D–1, and GL D–2 as the *31 CFR 560.540 List of Services, Software, and Hardware Incident to Communications* (the ''List''). The text of the List is provided below. Concurrently, OFAC is publishing an updated version of the List that will restrict the computing power of laptops, tablets, and personal computing devices authorized for exportation or reexportation to Iran under category (5) of the List, effective 30 days after publication in the **Federal Register**.

31 CFR 560.540 List of Services, Software, and Hardware Incident to Communications

Note: *See* paragraphs (a)(3)(ii)–(iii) of § 560.540 for authorizations related to certain hardware and software that is of a type described below but that is not subject to the Export Administration Regulations, 15 CFR parts 730 through 774 (EAR).

1. Mobile phones (including smartphones), Personal Digital Assistants (PDAs), Subscriber Identity Module/Subscriber Information Module (SIM) cards, and accessories for such devices designated EAR99 or classified on the CCL under ECCN 5A992.c; drivers and connectivity software for such hardware designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such hardware and software.

2. Satellite phones and Broadband Global Area Network (BGAN) hardware designated EAR99 or classified under ECCN 5A992.c; demand drivers and connectivity software for such hardware designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such hardware and software.

3. Consumer * modems, network interface cards, radio equipment (including antennae), routers, switches, and WiFi access points, designed for 50 or fewer concurrent users, designated EAR99 or classified under ECCNs 5A992.c, 5A991.b.2, or 5A991.b.4; drivers, communications, and connectivity software for such hardware designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such hardware and software.

4. Residential consumer* satellite terminals, transceiver equipment (including to antennae, receivers, set-top boxes and video decoders) designated EAR99 or classified under ECCNs 5A992.c, 5A991.b.2, or 5A991.b.4; drivers, communications, and connectivity software for such hardware designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such hardware and software.

5. Laptops, tablets, and personal computing devices, and peripherals for such devices (including consumer* disk drives and other data storage devices) and accessories for such devices (including keyboards and mice) designated EAR99 or classified on the CCL under ECCNs 5A992.c, 5A991.b.2, 5A991.b.4, or 4A994.b; computer operating systems and software required for effective consumer use of such hardware designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such hardware and software.

6. Anti-virus and anti-malware software designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such software.

7. Anti-tracking software designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such software.

8. Mobile operating systems, online application for mobile operating systems (app) stores, and related software, including apps designed to run on mobile operating systems, designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such software.

9. Anti-censorship tools and related software designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such software.

10. Virtual Private Network (VPN) client software, proxy tools, and fee-based client personal communications tools including voice, text, video, voice-over-IP telephony, video chat, and successor technologies, and communications and connectivity software required for effective consumer use designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such software.

11. Provisioning and verification software for Secure Sockets Layers (SSL) certificates designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such software.

Bradley T. Smith,

Director, Office of Foreign Assets Control.

[FR Doc. 2024–10722 Filed 5–16–24; 8:45 am]

BILLING CODE 4810–AL–P

* For purposes of the 31 CFR 560.540 List of Services, Software, and Hardware Incident to Communications, the term ''consumer'' refers to items that are: (1) generally available to the public by being sold, without restriction, from stock at retail selling points by means of any of the following: (a) over-the-counter transactions; (b) mail order transactions; (c) electronic transactions; or (d) telephone call transactions; and (2) designed for installation by the user without further substantial support by the supplier.

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Publication and Update of the List of Services, Software, and Hardware Incident to Communications

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication and update of a list of items determined to be incident to communications in the Iranian Transactions and Sanctions Regulations.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is updating a list of items published in the **Federal Register** that have been determined to be incident to communications and therefore authorized for export or reexport to Iran under a general license issued pursuant to the Iranian Transactions and Sanctions Regulations (ITSR). OFAC is updating the list to restrict the computing power of certain items on the list.

DATES: This list is effective June 17, 2024.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The text of the List of Services, Software, and Hardware Incident to Communications is available on the Iran Sanctions page on OFAC's website, and additional information concerning OFAC is available on OFAC's website (*www.treasury.gov/ofac*).

Background

Concurrent with this publication, OFAC published the list of items previously included in the annexes to GL D, GL D–1, and GL D–2 as ''List of Services, Software, and Hardware Incident to Communications under 31 CFR 560.540'' (the ''List''). OFAC is updating the List to add a technical restriction to the computing power of laptops, tablets, and personal computing devices authorized for exportation or reexportation to Iran under category (5) of the List, effective 30 days after publication. The text of the updated List is provided below.

''LIST OF SERVICES, SOFTWARE, AND HARDWARE INCIDENT TO COMMUNICATIONS UNDER 31 CFR 560.540''

[Updated June 17, 2024]

Note: *See* paragraphs (a)(3)(ii)–(iii) of § 560.540 for authorizations related to certain hardware and software that is of a type described below but that is not subject to the Export Administration Regulations, 15 CFR parts 730 through 774 (EAR).

1. Mobile phones (including smartphones), Personal Digital Assistants (PDAs), Subscriber Identity Module/Subscriber Information Module (SIM) cards, and accessories for such devices designated EAR99 or classified on the CCL under ECCN 5A992.c; drivers and connectivity software for such hardware designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such hardware and software.
2. Satellite phones and Broadband Global Area Network (BGAN) hardware designated EAR99 or classified under ECCN 5A992.c; demand drivers and connectivity software for such hardware designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such hardware and software.
3. Consumer* modems, network interface cards, radio equipment (including antennae), routers, switches, and WiFi access points, designed for 50 or fewer concurrent users, designated EAR99 or classified under ECCNs 5A992.c, 5A991.b.2, or 5A991.b.4; drivers, communications, and connectivity software for such hardware designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such hardware and software.
4. Residential consumer* satellite terminals, transceiver equipment (including to antennae, receivers, set-top boxes and video decoders) designated EAR99 or classified under ECCNs 5A992.c, 5A991.b.2, or 5A991.b.4; drivers, communications, and connectivity software for such hardware designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such hardware and software.
5. Laptops, tablets, and personal computing devices with an ''Adjusted Peak Performance'' (''APP'') not exceeding 1 Weighted TeraFLOP (WT), and peripherals for such devices (including consumer* disk drives and other data storage devices) and accessories for such devices (including keyboards and mice) designated EAR99 or classified on the CCL under ECCNs 5A992.c, 5A991.b.2, 5A991.b.4, or 4A994.b; computer operating systems and software required for effective consumer use of such hardware designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such hardware and software.
6. Anti-virus and anti-malware software designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such software.
7. Anti-tracking software designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such software.
8. Mobile operating systems, online application for mobile operating systems (app) stores, and related software, including apps designed to run on mobile operating systems, designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such software.
9. Anti-censorship tools and related software designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such software.
10. Virtual Private Network (VPN) client software, proxy tools, and fee-based client personal communications tools including voice, text, video, voice-over-IP telephony, video chat, and successor technologies, and communications and connectivity software required for effective consumer use designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such software.
11. Provisioning and verification software for Secure Sockets Layers (SSL) certificates designated EAR99 or classified under ECCN 5D992.c; and services necessary for the operation of such software.

*For purposes of the ''List of Services, Software, and Hardware Incident to Communications under 31 CFR 560.540,'' the term ''consumer'' refers to items that are: (1) generally available to the public by being sold, without restriction, from stock at retail selling points by means of any of the following: (a) over-the-counter transactions; (b) mail order transactions; (c) electronic transactions; or (d) telephone call transactions; and (2) designed for installation by the user without further substantial support by the supplier.

Bradley T. Smith,

Director, Office of Foreign Assets Control.

[FR Doc. 2024–10723 Filed 5–16–24; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Open Meeting of the Federal Advisory Committee on Insurance

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice of open meeting.

SUMMARY: This notice announces that the U.S. Department of the Treasury's Federal Advisory Committee on Insurance (FACI) will meet via videoconference on Tuesday, June 4, 2024, from 1 p.m.–3:30 p.m. eastern time. The meeting is open to the public. The FACI provides non-binding recommendation and advice to the Federal Insurance Office (FIO) in the U.S. Department of Treasury.

DATES: The meeting will be held via videoconference on Tuesday, June 4, 2024, from 1 p.m.–3:30 p.m. eastern time.

ADDRESSES: The meeting will be held via videoconference and is open to the public. The public can attend remotely via live webcast: *https://usdotyorktel.rev.vbrick.com/#/events/c9c165d4-7b16-4dc3-bceb-2810760a2db6.* The webcast will also be available through the FACI's website: *https://home.treasury.gov/policy-issues/financial-markets-financial-institutions-and-fiscal-service/federal-insurance-office/federal-advisory-committee-on-insurance-faci.* Please refer to the FACI website for up-to-date information on this meeting. Requests for reasonable accommodations under Section 504 of the Rehabilitation Act should be directed to Snider Page, Office of Civil Rights and Equal Employment Opportunity, Department of the Treasury at (202) 622–0341, or *snider.page@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: John Gudgel, Senior Insurance Regulatory Policy Analyst, Federal Insurance

Office, U.S. Department of the Treasury, 1500 Pennsylvania Ave. NW, Room 1410 MT, Washington, DC 20220, at (202) 622–1748 (this is not a toll-free number). Persons who have difficulty hearing or speaking may access this number via TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: Notice of this meeting is provided in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C. 1009(a)(2), through implementing regulations at 41 CFR 102–3.150.

Public Comment: Members of the public wishing to comment on the business of the FACI are invited to submit written statements by either of the following methods:

Electronic Statements

- Send electronic comments to *faci@treasury.gov.*

Paper Statements

- Send paper statements in triplicate to the Federal Advisory Committee on Insurance, U.S. Department of the Treasury, 1500 Pennsylvania Ave. NW, Room 1410 MT, Washington, DC 20220.

In general, the Department of the Treasury will make submitted comments available upon request without change, including any business or personal information provided such as names, addresses, email addresses, or telephone numbers. Requests for public comments can be submitted via email to *faci@treasury.gov.* The Department of the Treasury will also make such statements available for public inspection and copying in the Department of the Treasury's Library, 720 Madison Place NW, Room 1020, Washington, DC 20220, on official business days between the hours of 10 a.m. and 5 p.m. eastern time. You can make an appointment to inspect statements by telephoning (202) 622–2000. All statements received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. You should submit only information that you wish to make available publicly.

Tentative Agenda/Topics for Discussion: This will be the second FACI meeting of 2024. In this meeting, the FACI will discuss topics related to climate-related financial risk and the insurance sector, and will also discuss cyber insurance developments and international insurance issues. The FACI will also receive status updates from each of its subcommittees and from FIO on its activities, as well as consider any new business.

Dated: May 10, 2024.

Steven Seitz,

Director, Federal Insurance Office.

[FR Doc. 2024–10829 Filed 5–16–24; 8:45 am]

BILLING CODE 4810–AK–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0798]

Agency Information Collection Activity: Veteran/Beneficiary Claim for Reimbursement of Travel Expenses; Withdrawn

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice; withdrawal.

SUMMARY: On Tuesday, May 14, 2024 the Veterans Health Administration, Department of Veterans Affairs (VA), published a notice in the **Federal Register** announcing an opportunity for public comment on the proposed collection Veteran/Beneficiary Claim for Reimbursement of Travel Expenses (VA Form 10–3542 and BTSSS). This notice was published in error; therefore, this document corrects that error by withdrawing this FR notice, document number 2024–10461.

DATES: As of May 14, 2024, the FR notice published at 89 FR 42056 on Tuesday, May 14, 2024, is withdrawn.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.*

SUPPLEMENTARY INFORMATION: FR Doc. 2024–10461, published on May 14, 2024 (89 FR 42056), 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. 2024–10898 Filed 5–16–24; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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No. 97 May 17, 2024

Part II

Department of Homeland Security

Cybersecurity and Infrastructure Security Agency

42 CFR Part 512

Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 512

[CMS–5535–P]

RIN 0938–AU51

Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule describes a new mandatory Medicare payment model, the Increasing Organ Transplant Access Model (IOTA Model), that would test whether performance-based incentive payments paid to or owed by participating kidney transplant hospitals increase access to kidney transplants for patients with end-stage renal disease (ESRD) while preserving or enhancing the quality of care and reducing Medicare expenditures. This proposed rule also includes standard provisions that would apply to Innovation Center models whose first performance period begins on or after January 1, 2025, and also would apply, in whole or part, to any Innovation Center model whose first performance period begins prior to January 1, 2025 should such model's governing documentation incorporate the provisions by reference in whole or in part. The proposed standard provisions relate to beneficiary protections; cooperation in model evaluation and monitoring; audits and records retention; rights in data and intellectual property; monitoring and compliance; remedial action; model termination by CMS; limitations on review; miscellaneous provisions on bankruptcy and other notifications; and the reconsideration review process.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by July 16, 2024.

ADDRESSES: In commenting, please refer to file code CMS–5535–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–5535–P, P.O. Box 8013, Baltimore, MD 21244–8013.

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–5535–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: *CMMItransplant@cms.hhs.gov* for questions related to the Increasing Organ Transplant Access Model.

CMMI-StandardProvisions@cms.hhs.gov for questions related to the Standard Provisions for Innovation Center Models.

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 commenter will take actions to harm an individual. CMS encourages 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.

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I. Executive Summary

A. Purpose

Section 1115A of the Social Security Act (the Act) gives the Secretary of Health and Human Services the authority to test innovative payment and service delivery models to reduce program expenditures in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) while preserving or enhancing the quality of care furnished to individuals covered by such programs. This proposed rule describes a new mandatory Medicare payment model to be tested under section 1115A of the Act—the Increasing Organ Transplant Access Model (IOTA Model)—which would begin on January 1, 2025 and end on December 31, 2030. In this proposed rule, we propose payment policies, participation requirements, and other provisions to test the IOTA Model. We propose to test whether performance-based incentives (including both upside and downside risk) for participating kidney transplant hospitals can increase the number of kidney transplants (including both living donor and deceased donor transplants) furnished to End Stage Renal Disease (ESRD) patients, encourage investments in care processes and patterns with respect to patients who need kidney transplants, encourage investments in value-based care and improvement activities, and promote kidney transplant hospital accountability by tying payments to value. The IOTA Model is also intended to advance health equity by improving equitable access to the transplantation ecosystem through design features such as a proposed health equity plan requirement to address health outcome disparities and a health equity performance adjustment.

This proposed rule also includes proposed standard provisions that would apply to Innovation Center models whose first performance periods begin on or after January 1, 2025, unless otherwise specified in a model's governing documentation, as well as to Innovation Center models whose first performance periods begin prior to January 1, 2025, provided the standard provisions are incorporated into such models' governing documentation. The proposed standard provisions address beneficiary protections; cooperation in model evaluation and monitoring; audits and record retention; rights in data and intellectual property; monitoring and compliance; remedial action; model termination by CMS; limitations on review; miscellaneous provisions on bankruptcy and other

notifications; and the reconsideration review process.

We seek public comment on these proposals, the alternatives considered, and the request for information (RFI) in section III.D. of this proposed rule.

B. Summary of the Proposed Provisions

1. Standard Provisions for Innovation Center Models

The proposed standard provisions for Innovation Center models would be applicable to all Innovation Center models whose first performance periods begin on or after January 1, 2025, subject to any limitations specified in a model's governing documentation. The proposed standard provisions also would apply to all Innovation Center models whose first performance periods begin prior to January 1, 2025, provided the standard provisions are incorporated into such models' governing documentation.

We are proposing to codify these standard provisions to increase transparency, efficiency, and clarity in the operation and governance of Innovation Center models, and to avoid the need to restate the provisions in each model's governing documentation. The proposed standard provisions include terms that have been repeatedly memorialized, with minimal variation, in existing models' governing documentation. The proposed standard provisions are not intended to encompass all of the terms and conditions that would apply to each Innovation Center model, because each model embodies unique design features and implementation plans that may require additional, more tailored provisions, including with respect to payment methodology, care delivery and quality measurement, that would continue to be included in each model's governing documentation. Model-specific provisions applicable to the IOTA Model proposed herein are described in section III of this proposed rule.

2. Model Overview—Proposed Increasing Organ Transplant Access Model

a. Proposed IOTA Model Overview

End-Stage Renal Disease (ESRD) is a medical condition in which a person's kidneys cease functioning on a permanent basis, leading to the need for a regular course of long-term dialysis or a kidney transplant to maintain life.[1] The best treatment for most patients with kidney failure is kidney transplantation. Nearly 808,000 people in the United States are living with ESRD, with about 69 percent on dialysis and 31 percent with a kidney transplant.[2] For ESRD patients, regular dialysis sessions or a kidney transplant is required for survival. Relative to dialysis, a kidney transplant can improve survival, reduce avoidable health care utilization and hospital acquired conditions, improve quality of life, and lower Medicare expenditures.[3] [4] However, despite these benefits, evidence shows low rates of ESRD patients placed on kidney transplant hospitals' waitlists, a decline in living donors over the past 20 years, and underutilization of available donor kidneys, coupled with increasing rates of donor kidney discards, and wide variation in kidney offer acceptance rates and donor kidney discards by region and across kidney transplant hospitals.[5] [6] Further, there are substantial disparities in both deceased and living donor transplantation rates among structurally disadvantaged populations. Strengthening and improving the performance of the organ transplantation system is a priority for the Department of Health and Human Services (HHS). Consistent with this priority, and through joint efforts with HHS' Health Resources and Services Administration (HRSA), the proposed IOTA Model would aim to reduce Medicare expenditures and improve performance and equity in kidney transplantation by creating performance-based incentive payments for participating kidney transplant hospitals tied to access and quality of care for ESRD patients on the hospitals' waitlists.

The proposed IOTA Model would be a mandatory model that would begin on January 1, 2025 and end on December 31, 2030, resulting in a 6-year model performance period (''model performance period'') comprised of 6 individual performance years (each a ''performance year'' or ''PY''). The proposed IOTA Model would test whether performance-based incentives paid to, or owed by, participating kidney transplant hospitals can increase access to kidney transplants for patients with ESRD, while preserving or enhancing quality of care and reducing Medicare expenditures. CMS would select kidney transplant hospitals to participate in the IOTA Model through the methodology proposed in section III.C.3.d of this proposed rule. As this would be a mandatory model, the selected kidney transplant hospitals would be required to participate. CMS would measure and assess the participating kidney transplant hospitals' performance during each PY across three performance domains: achievement, efficiency, and quality.

The achievement domain would assess each participating kidney transplant hospital on the overall number of kidney transplants performed during a PY, relative to a participant-specific target. The efficiency domain would assess the kidney organ offer acceptance rates of each participating kidney transplant hospital relative to the national rate. The quality domain would assess the quality of care provided by the participating kidney transplant hospitals across a set of proposed outcome metrics and quality measures. Each participating kidney transplant hospital's performance score across these three domains would determine its final performance score and corresponding amount for the performance-based incentive payment that CMS would pay to, or the payment that would be owed by, the participating kidney transplant hospital. The proposed upside risk payment would be a lump sum payment paid by CMS after the end of a PY to a participating kidney transplant hospital with a final performance score of 60 or greater. Conversely, beginning after PY 2, the downside risk payment would be a lump sum payment paid to CMS by any participating kidney transplant hospital

[1] End-Stage Renal Disease (ESRD) | CMS. (n.d.). *https://www.cms.gov/medicare/coordination-benefits-recovery/overview/end-stage-renal-disease-esrd.*

[2] United States Renal Data System. 2022 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, 2022.

[3] Tonelli, M., Wiebe, N., Knoll, G., Bello, A., Browne, S., Jadhav, D., Klarenbach, S., & Gill, J. (2011). Systematic review: kidney transplantation compared with dialysis in clinically relevant outcomes. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 11*(10), 2093–2109. *https://doi.org/10.1111/j.1600-6143.2011.03686.xhttps://doi.org/10.1111/j.1600-6143.2011.03686.*

[4] Cheng, X. S., Han, J., Braggs-Gresham, J. L., Held, P. J., Busque, S., Roberts, J. P., Tan, J. C., Scandling, J. D., Chertow, G. M., & Dor, A. (2022). Trends in Cost Attributable to Kidney Transplantation Evaluation and Waitlist Management in the United States, 2012–2017. *JAMA network open, 5*(3), e221847. *https://doi.org/10.1001/jamanetworkopen.2022.184.*

[5] Al Ammary, F., Bowring, M. G., Massie, A. B., Yu, S., Waldram, M. M., Garonzik-Wang, J., Thomas, A. G., Holscher, C. M., Qadi, M. A., Henderson, M. L., Wiseman, A. C., Gralla, J., Brennan, D. C., Segev, D. L., & Muzaale, A. D. (2019). The changing landscape of live kidney donation in the United States from 2005 to 2017. *American journal of transplantation: official journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 19*(9), 2614–2621. *https://doi.org/10.1111/ajt.15368.*

[6] Mohan, S., Yu, M., King, K. L., & Husain, S. A. (2023). Increasing Discards as an Unintended Consequence of Recent Changes in United States Kidney Allocation Policy. *Kidney international reports, 8*(5), 1109–1111. *https://doi.org/10.1016/j.ekir.2023.02.1081.*

with a final performance score of 40 or lower. We are not proposing a downside risk payment for PY 1 of the model.

b. Model Scope

We propose that participation in the IOTA Model would be mandatory for 50 percent of all eligible kidney transplant hospitals in the United States. We anticipate that a total of approximately 90 kidney transplant hospitals will be selected to participate in the IOTA Model. As discussed in section III.C.3.b. of this proposed rule, we believe that mandatory participation is necessary to minimize the potential for selection bias and to ensure a representative sample size nationally, thereby guaranteeing that there will be adequate data to evaluate the model test.

We propose that eligible kidney transplant hospitals would be those that: (1) performed at least eleven kidney transplants for patients 18 years of age or older annually regardless of payer type during the three-year period ending 12 months before the model's start date; and (2) furnished more than 50 percent of the hospital's annual kidney transplants to patients 18 years of age or older during that same period. We propose to select the kidney transplant hospitals that will be required to participate in the IOTA Model from the group of eligible kidney transplant hospitals using a stratified random sampling of donation service areas (''DSAs'') to ensure that there is a fair selection process and representative group of participating kidney transplant hospitals. For the purposes of this proposed rule, a DSA has the same meaning given to that term at 42 CFR 486.302.

c. Performance Assessment

We propose to assess each IOTA participants' performance across three performance domains during each PY of the model, with a maximum possible final performance score of 100 points. The three performance domains would include: (1) an achievement domain worth up to 60 points, (2) an efficiency domain worth up to 20 points, and (3) a quality domain worth up to 20 points.

The achievement domain would assess the number of kidney transplants performed by each IOTA participant for attributed patients, with performance on this domain worth up to 60 points. The final performance score would be heavily weighted on the achievement domain to align with the IOTA Model's goal to increase access to kidney transplants. The IOTA Model theorizes that improvement activities, including those aimed at reducing unnecessary deceased donor discards and increasing living donors, may help increase access to kidney transplants.

We propose that CMS would set a target number of kidney transplants for each IOTA participant for each PY to measure the IOTA participant's performance in the achievement domain (the ''transplant target''), as described in section III.C.5.c of this proposed rule. Each IOTA participant's transplant target for a given PY would be based on the IOTA participant's historical volume of deceased and living donor transplants furnished to attributed patients in the relevant baseline years, adjusted by the national trend rate in the number of kidney transplants performed and further adjusted by the proportion of transplants furnished by the IOTA participant to attributed patients who are low income. Section III.C.5.c. of this proposed rule describes the variation in the number of kidney transplants performed across kidney transplant hospitals, which would make it challenging to set transplant targets on a regional or national basis. The IOTA Model would therefore set a transplant target that is specific to each IOTA participant to address this concern, while still accounting for the national trend rate in the number of kidney transplants performed. It is expected that IOTA participants' transplant targets may change from PY to PY because of the way in which the transplant target would be calculated.

The efficiency domain would assess the kidney organ offer acceptance rate ratio for each IOTA participant. The kidney organ offer acceptance rate ratio measures the number of kidneys an IOTA participant accepts for transplant over the expected value, based on variables such as kidney quality. Points for the kidney organ offer acceptance rate ratio would be determined relative to either the kidney organ offer acceptance rate ratio across all kidney transplant hospitals, or the IOTA participant's own past kidney organ offer acceptance rate ratio, with performance on the efficiency domain being worth up to 20 points.

Finally, the quality domain would assess IOTA participants' performance on post-transplant outcomes in addition to three quality measures—the CollaboRATE Shared Decision-Making Score, Colorectal Cancer Screening, and the 3-Item Care Transition Measure, with performance on this domain being worth up to 20 points.

Each IOTA participant's final performance score would be the sum of the points earned for each domain: achievement, efficiency, and quality. The final performance score in a PY would be determinative of whether the IOTA participant would be eligible to receive an upside risk payment from CMS, fall into the neutral zone where no upside or downside risk payment would apply, or owe a downside risk payment to CMS for the PY as described in section III.C.6. of this proposed rule.

d. Performance-Based Incentive Payment Formula

Each IOTA participant's final performance score would determine whether: (1) CMS would pay an upside risk payment to the IOTA participant; (2) the IOTA participant would fall into a neutral zone, in which case no performance-based incentive payment would be paid to or owed by the IOTA participant; or (3) the IOTA participant would owe a downside risk payment to CMS. For a final performance score above 60, CMS would apply the formula for the upside risk payment, which we propose would be equal to the IOTA participant's final performance score minus 60, then divided by 60, then multiplied by $8,000, then multiplied by the number of kidney transplants furnished by the IOTA participant to attributed patients with Medicare as their primary or secondary payer during the PY. Final performance scores below 60 in PY 1 and final performance scores of 41 to 59 in PYs 2–6 would fall in the neutral zone where there would be no payment owed to the IOTA participant or CMS.

We propose to phase-in the downside risk payment beginning in PY2. We explain in section III.C.5.b. of this proposed rule that new entrants to value-based payment models may need a ramp up period before they are able to accept downside risk. Thus, the IOTA Model proposes an upside risk-only approach for PY 1 as an incentive in each of the three performance domains. This would give IOTA participants time to consider, invest in, and implement value-based care and quality improvement initiatives before downside risk payments would begin. Beginning in PY 2, for a final performance score of 40 and below, CMS would apply the formula for the downside risk payment, which would be equal to the IOTA participant's final performance score minus 40, then divided by 40, then multiplied by −$2,000, then multiplied by the number of kidney transplants furnished by the IOTA participant to attributed patients with Medicare as their primary or secondary payer during the PY.

CMS would pay the upside risk payment in lump sum to the IOTA participant after the PY. The IOTA participant would pay the downside

risk payment to CMS in a lump sum after the PY.

e. Data Sharing

We propose to collect certain quality, clinical, and administrative data from IOTA participants for model monitoring and evaluation activities under the authority in 42 CFR 403.1110(b). We would also share certain data with IOTA participants upon request as described in section III.C.3.a. of this proposed rule and as permitted by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule and other applicable law. We propose to offer each IOTA participant the opportunity to request certain beneficiary-identifiable data for their attributed Medicare beneficiaries for treatment, case management, care coordination, quality improvement activities, and population-based activities relating to improving health or reducing health care costs, as permitted by 45 CFR 164.506(c). The data uses and sharing would be allowed only to the extent permitted by the HIPAA Privacy Rule and other applicable law and CMS policies. We also propose to share certain aggregate, de-identified data with IOTA participants.

f. Other Requirements

We propose several other model requirements for selected transplant hospitals, including transparency requirements, public reporting requirements, and a health equity plan requirement which would be optional for PY1 and required for PY 2 through PY 6, as described in section III.C.8. of this proposed rule.

(1) Transparency Requirements

Patients are often unsure whether they qualify for a kidney transplant at a given kidney transplant hospital. We propose that IOTA participants would be required to publish on a public facing website the criteria they use when determining whether or not to add a patient to the kidney transplant waitlist. We also propose to add requirements to facilitate increased transparency for patients regarding the organ offers received on the patient's behalf while the patient is on the waitlist. Specifically, we propose that IOTA participants would be required to inform patients on the waitlist, on a monthly basis, of the number of times an organ was declined on each patient's behalf and the reason(s) why each organ was declined. We believe that notifying patients of the organs declined on their behalf would encourage conversations between patients and their providers regarding a patient's preferences for transplant and facilitate better shared decision-making.

(2) Health Equity Requirements

We propose that during the model's first PY, each IOTA participant would have the option to submit a health equity plan (''HEP'') to CMS. We propose that each IOTA participant would then be required to submit a HEP to CMS for PY 2 and to update its HEP for each subsequent PY. We propose that the IOTA participant's HEP would identify health disparities within the IOTA participant's population of attributed patients and outline a course of action to address them.

We also considered proposing to require IOTA participants to collect and report patient-level health equity data to CMS. Specifically, we considered proposing that IOTA participants would be required to conduct health related social needs screening for at least three core areas—food security, housing, and transportation. We recognize these areas as some of the most common barriers to kidney transplantation and the most pertinent health related social needs for the IOTA patient population.[7] We have included an RFI in this proposed rule to solicit feedback and comment on such a requirement.

g. Medicare Payment Waivers and Additional Flexibilities

We believe it is necessary to waive certain requirements of title XVIII of the Act solely for purposes of carrying out the testing of the IOTA Model under section 1115A of the Act. We propose to issue these waivers using our waiver authority under section 1115A(d)(1) of the Act. Each of the proposed waivers is discussed in detail in section III.C.10. of this proposed rule.

h. Overlaps With Other Innovation Center Models and CMS Programs

We expect that there could be situations where a Medicare beneficiary attributed to an IOTA participant is also assigned, aligned, or attributed to another Innovation Center model or CMS program. Overlap could also occur among providers and suppliers at the individual or organization level, such as where an IOTA participant or one of their providers would participate in multiple Innovation Center models. We believe that the IOTA Model would be compatible with existing models and programs that provide opportunities to improve care and reduce spending. The IOTA Model would not be replacing any covered services or changing the payments that participating hospitals receive through the inpatient prospective payment system (IPPS) or outpatient prospective payment system (OPPS). Rather, the IOTA Model proposes performance-based payments separate from what participants would be paid by CMS for furnishing kidney transplants to Medicare beneficiaries. Additionally, we would work to resolve any potential overlaps between the IOTA Model and other Innovation Center models or CMS programs that could result in duplicative payments for services, or duplicative counting of savings or other reductions in expenditures. Therefore, we propose to allow overlaps between the IOTA Model and other Innovation Center models and CMS programs.

i. Monitoring

We propose to closely monitor the implementation and outcomes of the IOTA Model throughout its duration consistent with the monitoring requirements proposed in the Standard Provisions for Innovation Center models in section II of this proposed rule and the proposed requirements in section III.C.13. of this proposed rule. The purpose of this monitoring would be to ensure that the IOTA Model is implemented safely and appropriately, that the quality and experience of care for beneficiaries is not harmed, and that adequate patient and program integrity safeguards are in place.

j. Beneficiary Protections

As proposed in section III.C.10. of this proposed rule, CMS would not allow beneficiaries or patients to opt out of attribution to an IOTA participant; however, the IOTA Model would not restrict a beneficiary's freedom to choose another kidney transplant hospital, or any other provider or supplier for healthcare services, and IOTA participants would be subject to the Standard Provisions for Innovation Center Models outlined in section II. of this proposed rule protecting Medicare beneficiary freedom of choice and access to medically necessary services. We also would require that IOTA participants notify Medicare beneficiaries of the IOTA participant's participation in the IOTA Model by, at a minimum, prominently displaying informational materials in offices or facilities where beneficiaries receive care. Additionally, IOTA participants would be subject to the proposed Standard Provisions for Innovation Center Models regarding descriptive model materials and activities in section II. of this proposed rule.

[7] Venkataraman, S., & Kendrick, J. (2020). Barriers to kidney transplantation in ESKD. *Seminars in Dialysis, 33*(6), 523–532. *https://doi.org/10.1111/sdi.12921.*

C. Summary of Costs and Benefits

The IOTA Model aims to incentivize transplant hospitals to overcome system-level barriers to kidney transplantation. The chronic shortfall in kidney transplants results in poorer outcomes for patients and increases the burden on Medicare in terms of payments for dialysis and dialysis-based enrollment in the program. There is reasonable evidence that the savings to Medicare resulting from an incremental growth in transplantation would potentially exceed the payments projected under the model's proposed incentive structure.

II. Standard Provisions for Innovation Center Models

A. Introduction

Section 1115A of the Act authorizes the Center for Medicare and Medicaid Innovation (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. We have designed and tested both voluntary Innovation Center models—governed by participation agreements, cooperative agreements, and model-specific addenda to existing contracts with CMS—and mandatory Innovation Center models that are governed by regulations. Each voluntary and mandatory model features its own specific payment methodology, quality metrics, and certain other applicable policies, but each model also features numerous provisions of a similar or identical nature, including provisions regarding cooperation in model evaluation; monitoring and compliance; and beneficiary protections.

On September 29, 2020, we published in the **Federal Register** a final rule titled ''Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures'' (85 FR 61114) (hereinafter the ''Specialty Care Models final rule''), in which we adopted General Provisions Related to Innovation Center models at 42 CFR part 512 subpart A that apply to the End-Stage Renal Disease Treatment Choices (ETC) Model and the Radiation Oncology (RO) Model.[8] The Specialty Care Models final rule codified general provisions regarding beneficiary protections, cooperation in model evaluation and monitoring, audits and record retention, rights in data and intellectual property, monitoring and compliance, remedial action, model termination by CMS, limitations on review, and bankruptcy and other notifications. These general provisions were adopted only for the ETC and RO Models (and, in practice, applied only to the ETC Model). However, we now believe the general provisions should apply to Innovation Center models more broadly. As we note, the Innovation Center models share numerous similar provisions, and codifying the general provisions into law to expand their applicability across models, except where otherwise explicitly specified in a model's governing documentation, would, we believe, promote transparency, efficiency, clarity, and ensure consistency across models to the extent appropriate, while avoiding the need to restate the provisions in each model's governing documentation.

We also propose a new provision pertaining to the reconsideration review process that would apply to Innovation Center models that waive the appeals processes provided under section 1869 of the Act.

B. General Provisions Codified in the Code of Federal Regulations That Would Apply to Innovation Center Models

Each Innovation Center model features many unique aspects that must be memorialized in its governing documentation, but each model also includes certain provisions that are common to most or all models. We believe that codifying these common provisions would facilitate their uniform application across models (except where the governing documentation for a particular model dictates otherwise) and promote program efficiency and consistency that would benefit CMS' program administration and model participants.

As such, we propose to expand the applicability of the 42 CFR part 512 subpart A ''General Provisions Related to Innovation Center Models'' to all Innovation Center models whose first performance periods begin on or after January 1, 2025, unless otherwise specified in the models' governing documentation, and also to any Innovation Center models whose first performance periods begin prior to January 1, 2025 if incorporated by reference into the models' governing documentation. To accomplish this, we propose that the provisions codified at 42 CFR part 512 subpart A for the ETC and RO Models, including those with respect to definitions, beneficiary protections, cooperation in model evaluation and monitoring, audits and record retention, rights in data and intellectual property, monitoring and compliance, remedial action, Innovation Center model termination by CMS, and limitations on review, would be designated as the newly defined ''standard provisions for Innovation Center models'' and would apply to all Innovation Center models as described

[8] In the autumn of 2020, due to the Secretary of Health and Human Services' Determination that a Public Health Emergency Exists for the Coronavirus disease 2019 (COVID–19) (*https://aspr.hhs.gov/legal/PHE/Pages/2019-nCoV.aspx*), CMS revised the RO Model's performance period to begin on July 1, 2021, and to end on December 31, 2025, in the CY 2021 Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems and Quality Reporting Programs final rule with comment period (85 FR 85866). Section 133 of the Consolidated Appropriations Act (CAA), 2021 (Pub. L. 116–260) (hereinafter referred to as ''CAA, 2021''), enacted on December 27, 2020, included a provision that prohibited implementation of the RO Model before January 1, 2022. This congressional action superseded the July 1, 2021, start date that we had established in the CY 2021 OPPS/ASC IFC. To align the RO Model regulations with the requirements of the CAA, 2021, we proposed to modify the definition of ''model performance period'' in 42 CFR part 512.205 to provide for a 5-year model performance period starting on January 1, 2022, unless the RO Model was prohibited by law from starting on January 1, 2022, in which case the model performance period would begin on the earliest date permitted by law that is January 1, April 1, or July 1. We also proposed other modifications both related and unrelated to the timing of the RO Model in the proposed rule that appeared in the August 4, 2021, **Federal Register** titled ''Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals'' (86 FR 42018). These provisions were finalized in a final rule with comment period titled ''Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model'' that appeared in the November 16, 2021 **Federal Register** (86 FR 63458) (hereinafter referred to as the ''CY 2022 OPPS/ASC FC'').

On December 10, 2021, the Protecting Medicare and American Farmers from Sequester Cuts Act (Pub. L. 117–71) was enacted, which included a provision that prohibits implementation of the RO Model prior to January 1, 2023. The CY 2022 OPPS/ASC final rule with comment period specified that if the RO Model was prohibited by law from beginning on January 1, 2022, the model performance period would begin on the earliest date permitted by law that is January 1, April 1, or July 1. As a result, under the current definition for model performance period at § 512.205, the RO Model would have started on January 1, 2023, because that date is the earliest date permitted by law. However, given the multiple delays to date, and because both CMS and RO participants must invest operational resources in preparation for implementation of the RO Model, we have considered how best to proceed under these circumstances. In a final rule titled ''Radiation Oncology (RO) Model,'' which appeared in the **Federal Register** on August 29, 2022 (87 FR 52698), we delayed the start date of the RO Model to a date to be determined through future rulemaking, and modified the definition of the model performance period at § 512.205 to provide that the start and end dates of the model performance period for the RO Model would be established in future rulemaking. We have not undertaken rulemaking to determine the start date for the RO Model and, thus, the model is not active at this time.

above. We propose specific revisions that would be necessary to expand the scope of several of the current general provisions, but otherwise propose that the general provisions (which would be referred to as the ''standard provisions for Innovation Center models'') would not change. In particular, we propose that the substance of the following provisions would not change, except that they would apply to all Innovation Center Models as opposed to just the ETC and RO Models: § 512.120 Beneficiary protections; § 512.130 Cooperation in model evaluation and monitoring; § 512.135 Audits and record retention; § 512.140 Rights in data and intellectual property: § 512.150 Monitoring and compliance; § 512.160 Remedial action; § 512.165 Innovation center model termination by CMS; § 512.170 Limitations on review; and § 512.180 Miscellaneous provisions on bankruptcy and other notifications.

C. Proposed Revisions to the Titles, Basis and Scope Provision, and Effective Date

We propose to amend the title of part 512 to read ''Standard Provisions for Innovation Center Models and Specific Provisions for the Radiation Oncology Model and the End Stage Renal Disease Model'' so that it more closely aligns with the other changes proposed herein and to ensure that the title indicates that part 512 includes both standard provisions for Innovation Center models and specific provisions for the RO and ETC Models. We also propose to amend the title of subpart A to read ''Standard Provisions for Innovation Center Models'' to use the term we propose to define the provisions codified at 42 CFR part 512 subpart A.

Additionally, we propose to amend § 512.100(a) and (b) so that the standard provisions would take effect on January 1, 2025, and would apply to each Innovation Center model where that model's first performance period begins on or after January 1, 2025, unless the model's governing documentation indicates otherwise, as well as any Innovation Center model that begins testing its first performance period prior to January 1, 2025, if the model's governing documentation incorporates the provisions by reference in whole or in part. We propose to determine on a case-by-case basis, based on each model's unique features and design, whether the standard provisions would apply to a particular model, or whether we would specify alternate terms in the model's governing documentation.

We believe that these standard provisions are necessary for the testing of the IOTA model, regardless of whether they are finalized as proposed for all Innovation Center models. As such, as an alternative to the previous proposal, we would propose making these standard provisions for Innovation Center models applicable to, and effective for, the IOTA Model beginning on January 1, 2025, absent extending the standard provisions to all Innovation Center models. Under such an alternative, the general provisions in the Specialty Care Models final rule would also still be applicable to the ETC Model and the RO Model.

These proposed standard provisions would not, except as specifically noted in this section II. of this proposed rule, affect the applicability of other provisions affecting providers and suppliers under Medicare fee-for-service (FFS).

We invite public comment on these proposed changes.

D. Provisions Revising Certain Definitions

We propose to amend the definition of ''Innovation Center model'' at 42 CFR 512.110 by replacing the specific references to the RO and ETC Models with a definition consistent with section 1115A of the Act and intended to encompass all Innovation Center models. We propose to amend the definition for ''Innovation Center model'' to read as follows: ''an innovative payment and service delivery model tested under the authority of section 1115A(b) of the Act, including a model expansion under section 1115A(c) of the Act.''

We propose to add a new definition of the term ''governing documentation'' at § 512.110 to mean, ''the applicable Federal regulations, and the model-specific participation agreement, cooperative agreement, and any addendum to an existing contract with CMS, that collectively specify the terms of the Innovation Center model.'' We propose to add a new definition, ''standard provisions for Innovation Center models,'' at § 512.110 to mean, ''the provisions codified in 42 CFR 512 Subpart A.'' We propose to add a new definition, ''performance period,'' at § 512.110 to mean, ''the period of time during which an Innovation Center model is tested and model participants are held accountable for cost and quality of care; the performance period for each Innovation Center model is specified in the governing documentation.''

Further, we propose to amend the definitions of ''Innovation Center model activities,'' ''model beneficiary,'' and ''model participant'' to pertain to all ''Innovation Center models,'' as we propose to define that term, instead of just the models previously implemented under part 512. As such, we propose to define ''Innovation Center model activities'' to mean ''any activities affecting the care of model beneficiaries related to the test of the Innovation Center model.'' We propose to define ''model beneficiary'' to mean ''a beneficiary attributed to a model participant or otherwise included in an Innovation Center model.'' We propose to define ''model participant'' to mean ''an individual or entity that is identified as a participant in the Innovation Center model.''

We invite public comment on these proposed changes to the definitions of ''Innovation Center model,'' ''Innovation Center model activities,'' ''model beneficiary,'' and ''model participant'' and the proposed definitions of ''governing documentation,'' ''standard provisions for Innovation Center models,'' and ''performance period.''

E. Proposed Reconsideration Review Process

We propose to add a new § 512.190 to part 512 subpart A to codify a reconsideration review process, based on processes implemented under current Innovation Center models. The process would enable model participants to contest determinations made by CMS in certain Innovation Center models, where model participants would not otherwise have a means to dispute determinations made by CMS. We propose at § 512.190(a)(1) that such a reconsideration process would apply only to Innovation Center models that waive section 1869 of the Act, which governs determinations and appeals in Medicare, or where section 1869 would not apply because model participants are not Medicare-enrolled. We propose at § 512.190(a)(2) that only model participants may utilize the dispute resolution process, unless the governing documentation for the Innovation Center model states otherwise. Such limitations with respect to such models are, we believe, appropriate, because with respect to such models, model participants do not have another means to dispute determinations made by CMS. We propose to codify a reconsideration review process in regulation in order to have a transparent and consistent method of reconsideration for model participants participating in models that do not utilize the standard reconsideration process outlined in section 1869 of the Act.

This proposed reconsideration review process would be utilized where a model-specific determination has been made and the affected model participant

disagrees with, and wishes to challenge, that determination. Each Innovation Center model features a unique payment and service delivery model, and, as such, requires its own model-specific determination process. Each Innovation Center model's governing documentation details the model-specific determinations made by CMS, which may include, but are not limited to, model-specific payments, beneficiary attribution, and determinations regarding remedial actions. Each Innovation Center model's governing documentation also includes specific details about when a determination is final and may be disputed through the model's reconsideration review processes.

We propose at § 512.190(b) that model participants may request reconsideration of a determination made by CMS in accordance with an Innovation Center model's governing documentation only if such reconsideration is not precluded by section 1115A(d)(2) of the Act, part 512 subpart A, or the model's governing documentation. A model participant may challenge, by requesting review by a CMS reconsideration official, those final determinations made by CMS that are not precluded from administrative or judicial review. We propose at § 512.190(b)(i) that the CMS reconsideration official would be someone who is authorized to receive such requests and was not involved in the initial determination issued by CMS or, if applicable, the timely error notice review process. We propose at § 512.190(b)(ii) that the reconsideration review request would be required to include a copy of CMS's initial determination and contain a detailed written explanation of the basis for the dispute, including supporting documentation. We propose at § 512.190(b)(iii) that the request for reconsideration would have to be made within 30 days of the date of CMS' initial determination for which reconsideration is being requested via email to an address as specified by CMS in the governing documentation. At § 512.190(b)(2), we propose that requests that do not meet the requirements of paragraph (b)(1) would be denied.

We propose at § 512.190(b)(3) that the reconsideration official would send a written acknowledgement to CMS and to the model participant requesting reconsideration within 10 business days of receiving the reconsideration request. The acknowledgement would set forth the review procedures and a schedule that would permit each party an opportunity to submit position papers and documentation in support of its position for consideration by the reconsideration official.

We propose to codify at § 512.190(b)(4) that, to access the reconsideration process for a determination concerning a model-specific payment where the Innovation Center model's governing documentation specifies an initial timely error notice process, the model participant must first satisfy those requirements before submitting a reconsideration request under this process. Should a model participant fail to timely submit an error notice with respect to a particular model-specific payment, we propose that the reconsideration review process would not be available to the model participant with regard to that model-specific payment.

We propose to codify standards for reconsideration at § 512.190(c). First, during the course of the reconsideration, we propose that both CMS and the party requesting the reconsideration must continue to fulfill all responsibilities and obligations under the governing documentation during the course of any dispute arising under the governing documentation. Second, the reconsideration would consist of a review of documentation timely submitted to the reconsideration official and in accordance with the standards specified by the reconsideration official in the acknowledgement at § 512.190(b)(3). Finally, we propose that the model participant would bear the burden of proof to demonstrate with clear and convincing evidence to the reconsideration official that the determination made by CMS was inconsistent with the terms of the governing documentation.

We propose to codify at § 512.190(d) that the reconsideration determination would be an on-the-record review. By this, we mean a review that would be conducted by a CMS reconsideration official who is a designee of CMS who is authorized to receive such requests under proposed § 512.190(b)(1)(i), of the position papers and supporting documentation that are timely submitted and in accordance with the schedule specified under proposed § 512.190(b)(3)(ii) and that meet the standards of submission under proposed § 512.190(b)(1) as well as any documents and data timely submitted to CMS by the model participant in the required format before CMS made the initial determination that is the subject of the reconsideration request. We propose at § 512.190(d)(2) that the reconsideration official would issue to the parties a written reconsideration determination. Absent unusual circumstances, in which the reconsideration official would reserve the right to an extension upon written notice to the model participant, the reconsideration determination would be issued within 60 days of CMS's receipt of the timely filed position papers and supporting documentation in accordance with the schedule specified under proposed § 512.190(b)(3)(ii). Under proposed § 512.190(d)(3), the determination made by the CMS reconsideration official would be final and binding 30 days after its issuance, unless the model participant or CMS were to timely request review of the reconsideration determination by the CMS Administrator in accordance with §§ 512.190(e)(1) and (2).

We propose to codify at § 512.190(e) a process for the CMS Administrator to review reconsideration determinations made under § 512.190(d). We propose that either the model participant or CMS may request that the CMS Administrator review the reconsideration determination. The request to the CMS Administrator would have to be made via email, within 30 days of the reconsideration determination, to an email address specified by CMS. The request would have to include a copy of the reconsideration determination, as well as a detailed written explanation of why the model participant or CMS disagrees with the reconsideration determination. The CMS Administrator would promptly send the parties a written acknowledgement of receipt of the request for review. The CMS Administrator would send the parties notice of whether the request for review was granted or denied. If the request for review is granted, the notice would include the review procedures and a schedule that would permit each party to submit a brief in support of the party's positions for consideration by the CMS Administrator. If the request for review is denied, the reconsideration determination would be final and binding as of the date of denial of the request for review by the CMS Administrator. If the request for review by the CMS Administrator is granted, the record for review would consist solely of timely submitted briefs and evidence contained in the record of the proceedings before the reconsideration official and evidence as set forth in the documents and data described in proposed § 512.190(d)(1)(ii); the CMS Administrator would not consider evidence other than information set forth in the documents and data described in proposed § 512.190(d)(1)(ii). The CMS

Administrator would review the record and issue to the parties a written determination that would be final and binding as of the date the written determination is sent.

We invite public comment on the proposed reconsideration review process for Innovation Center models.

III. Proposed Increasing Organ Transplant Access (IOTA) Model

A. Introduction

In this proposed rule, we are proposing to test the IOTA Model, a new mandatory Medicare alternative payment model under the authority of the Innovation Center, that would begin on January 1, 2025, and end on December 31, 2030. The IOTA Model would test whether using performance-based incentive payments in the form of upside risk payments and downside risk payments to and from select transplant hospitals increases the number of kidney transplants furnished to patients with ESRD, thereby reducing Medicare expenditures while preserving or enhancing quality of care.

The goal of the proposed performance-based payments is: to increase the number of kidney transplants furnished to ESRD patients placed on a kidney transplant hospital's waitlist; encourage investments in value-based care and quality improvement activities, particularly those that promote an equitable kidney transplant process prior to, during, and post transplantation for all patients; encourage better use of the current supply of deceased donor organs and greater provider and community collaborations to address medical and non-medical needs of patients; and increased awareness, education, and support for living donations. The IOTA Model payment structure would also promote IOTA participant accountability by linking performance-based payments to quality. We theorize that increasing the number of kidney transplants furnished to ESRD patients on the participating hospitals' waitlists would reduce Medicare expenditures by reducing dialysis expenditures and avoidable health care service utilization and would improve the quality of life for patients with ESRD.

As discussed in section III.B of this proposed rule, studies show that kidney transplant hospitals are underutilizing donor kidneys and have become more conservative in accepting organs for transplantation, with notable variation by region and across transplant hospitals.[9] The IOTA Model aims to address these access and equity problems through financial incentives that reward IOTA participants that improve their kidney organ offer acceptance rate ratios over time or hold them financially accountable for not doing so. The IOTA Model's proposed payment structure would include upside or downside performance-based incentive payments (''upside risk payment'' or ''downside risk payment'') for kidney transplant hospitals selected to participate in the IOTA Model (''IOTA participant''), with these payments being tied to performance on achievement, efficiency, and quality domains.

The achievement domain would assess the number of kidney transplants performed relative to a participant-specific target, with performance on this domain being worth up to 60 points. The efficiency domain would assess kidney organ offer acceptance rate ratios relative to a national rate for all kidney transplant hospitals, including those not selected to participate in the model, with performance on this domain being worth up to 20 points. The quality domain would assess performance based on post-transplant outcomes at one-year after transplant and a proposed set of quality measures, with performance on this domain being worth up to 20 points. The achievement domain would be weighted more heavily than the other two domains because increasing the number of transplants is a key goal of the model and would be a primary factor in determining the amount of the performance-based payment.

The final performance score for each IOTA participant would be the sum of the points earned across the achievement domain, efficiency domain, and quality domain. The final performance score would determine whether an upside risk payment or downward risk payment would be owed and the amount of such payment. Specifically:

- For PY 1, if an IOTA participant has a final performance score between 60 and 100 points, it would qualify for the upside risk payment in accordance with the proposed calculation methodology described in section III.C.6.c(a) of this proposed rule (final performance score minus 60, then divided by 60, then multiplied by $8,000, then multiplied by the number of kidney transplants furnished by the IOTA participant to beneficiaries with Medicare as a primary or secondary payer during the PY).
- For PY 1, if an IOTA participant has a final performance score below 60, it would fall into a neutral zone where no upside risk payment and no downside risk payment would apply.
- For PY 2 and each subsequent PY (PYs 2–6) if an IOTA participant achieves a final performance score of 41 to 59 points, it would fall into a neutral zone where no upside risk payment and no downside risk payment would apply.
- For PY 2 and each subsequent PY, if an IOTA participant achieves a final performance score of 40 points or below, it would qualify for the downside risk payment in accordance with the proposed calculation methodology described in section III.C.6.c.(b). of this proposed rule (final performance score minus 40, then divided by 40, then multiplied by −$2,000, then multiplied by the number of kidney transplants furnished by the IOTA participant to beneficiaries with Medicare as a primary or secondary payer during the PY).

We recognize the complexity of the transplant ecosystem, which requires coordination between transplant hospitals, other health care providers, organ procurement organizations (OPOs), patients, potential donors, and their families. The proposed IOTA Model does not prescribe or require specific processes or policy approaches that each selected IOTA participant must implement for purposes of the model test.

We believe the IOTA Model would complement other efforts in relation to the transplant ecosystem to enhance health and safety outcomes, increase transparency, increase the number of transplants, and reduce disparities. We also believe that the proposed payment methodology would act in concert with measures that are currently under development by HRSA to increase the numbers of both deceased and living donor organ transplants.

This proposed model falls within a larger framework of activities initiated by the Federal Government during the past several years and planned for the upcoming year to enhance the donation, procurement, and transplantation of solid organs. This Federal collaborative, called the Organ Transplantation Affinity Group (OTAG), is a coordinated group working together to strengthen accountability, equity, and performance in organ donation, procurement, and transplantation.[10]

[9] Mohan, S., Chiles, M.C., Patzer, R.E., Pastan, S.O., Husain, S.A., Carpenter, D.J., Dube, G.K., Crew, R.J., Ratner, L.E., & Cohen, D.J. (2018). Factors leading to the discard of deceased donor kidneys in the United States. *Kidney International, 94*(1), 187–198. *https://doi.org/10.1016/j.kint.2018.02.016.*

[10] Moody-Williams, J.D., & Nair, S. (2023, September 15). Organ Transplantation Affinity

Continued

B. Background

A review of the literature on kidney transplantation shows that the increasing numbers of kidney transplants is unable to keep pace with the increasing need for organs.[11] While more people die waiting for a kidney transplant, the short- and long-term outcomes of patients who undergo kidney transplantation have improved, despite both recipients and donors increasing in age and adverse health conditions.[12] Recent studies show that transplant hospitals have become more conservative in accepting organs for transplantation when offered for specific patients, avoiding the use of less-than-ideal organs on account of perceived risk.[13] Wide variation among geographic regions and transplant hospitals in rates of kidney transplantation, along with access and equity issues, raises the need to hold kidney transplant hospitals accountable for performance.[14] The IOTA Model proposes a two-sided performance-based payment structure that rewards IOTA participants for high performance in the achievement, efficiency, and quality domains, and imposes financial accountability on IOTA participants that perform poorly on those domains. We propose the IOTA Model as a complement to wider efforts aimed at transplant ecosystem performance and equity improvements. Ultimately, we seek a set of interventions that focus on ESRD patients in need of a kidney transplant. In this section of the proposed rule, we summarize the transplant ecosystem and HHS oversight within CMS and HRSA related to kidney transplantation, highlight related initiatives and priorities nationally, and outline our rationale for the proposed IOTA Model informed by literature, data, and studies.

1. The Transplant Ecosystem

Kidney transplantation occurs within an overall organ donation and transplantation system (also known and referred to as the transplant ecosystem) that comprises a vast network of institutions dedicated to ensuring that patients are evaluated and, if appropriate, placed onto the organ transplant waitlist, and that those on the organ transplant waitlist receive lifesaving organ transplants. Transplantation of livers, hearts, lungs, and other organs is also well established within the U.S. health care system. The transplant ecosystem includes the Organ Procurement and Transplantation Network (OPTN); Organ Procurement Organizations (OPOs); transplant hospitals and providers; histocompatibility laboratories that provide blood, tissue, and antibody testing for the organ matching process; and patients, including ESRD patients in need of a transplant, their families, and caregivers.[15] For kidney transplantation, it also includes ESRD facilities, commonly known as dialysis facilities.

The National Organ Transplant Act of 1984, referred to herein as NOTA, established the OPTN, with HHS oversight, to manage and operate the national organ transplantation system (42 U.S.C. 274). The OPTN coordinates the nation's organ procurement, distribution, and transplantation systems. The OPTN is a network of clinical experts, patients, donor families, and community stakeholders who work collectively to develop, implement, and monitor organ allocation policy and performance of the organ transplant ecosystem.

Organ Procurement Organizations (OPOs) are non-profit organizations operating under contract with the Federal Government that are charged, under section 371(b) of the Public Health Service Act (PHS Act, 42 U.S.C. 273(b)) with activities including, but not limited to, identifying potential organ donors, providing for the acquisition and preservation of donated organs, the equitable allocation of donated organs, and the transportation of donated organs to transplant hospitals. Section 371(b) of the Public Health Services Act requires that an OPO must have a defined service area, a concept that is defined at 42 CFR part 486 subpart G as the Donation Service Area (DSA). Section 1138(b) of the Act states that the Secretary may not designate more than one OPO to serve each DSA. There are currently 56 OPOs that serve the United States and Puerto Rico.

Section 1138(b) of the Act lays out the requirements that an OPO must meet to have its costs reimbursed by the Secretary. CMS sets out the components of allowable Medicare organ acquisition costs at 42 CFR 413.402(b). Allowable organ acquisition costs are those costs incurred in the acquisition of organs intended for transplant, and include, but are not limited to: costs associated with special care services, the surgeon's fee for excising the deceased donor organ from the donor patient (limited to $1,250 for kidneys), operating room and other inpatient ancillary services provided to the living or deceased donor, organ preservation and perfusion costs, donor and beneficiary evaluation, and living donor complications. OPOs and transplant hospitals may incur organ acquisition costs and include these and some additional administrative and general costs on the Medicare cost report.

The CMS conditions for coverage for OPOs at 42 CFR 486.322 require an OPO to have written agreements with 95 percent of the Medicare and Medicaid certified hospitals and critical access hospitals in its DSA that have a ventilator and an operating room and have not been granted a waiver to work with another OPO. These hospitals, known as donor hospitals, are required by the CMS conditions of participation for hospitals at 42 CFR 482.45 to have an agreement with an OPO under which the donor hospital must notify the OPO of patients who are expected to die imminently and of patients who have died in the hospital. (Under the hospital conditions of participation, such an agreement is required of all hospitals that participate in Medicare.) Also, under the hospital conditions of participation, donor hospitals are responsible for informing donor patient families of the option to donate organs, tissues, and eyes, or to decline to donate; and to work collaboratively with the OPO to educate hospital staff on donation, improve its identification of potential donors, and work with the OPO to manage the potential donor patient while testing and placement of the potential donor organ occurs.

At 42 CFR 482.70, CMS defines a transplant hospital as ''a hospital that furnishes organ transplants and other medical and surgical specialty services

Group (OTAG): Strengthening accountability, equity, and performance √ CMS. *BLOG. https://www.cms.gov/blog/organ-transplantation-affinity-group-otag-strengthening-accountability-equity-and-performance.*

[11] Too Many Donor Kidneys Are Discarded in U.S. Before Transplantation—Penn Medicine. (2020, December 16). *www.pennmedicine.org. https://www.pennmedicine.org/news/news-releases/2020/december/too-many-donor-kidneys-are-discarded-in-us-before-transplantation.*

[12] Hariharan, S., Israni, A.K., & Danovitch, G. (2021). Long-Term Survival after Kidney Transplantation. *New England Journal of Medicine, 385*(8), 729–743. *https://doi.org/10.1056/nejmra2014530.*

[13] Stewart, D.E., Garcia, V.C., Rosendale, J.D., Klassen, D.K., & Carrico, B.J. (2017). Diagnosing the Decades-Long Rise in the Deceased Donor Kidney Discard Rate in the United States. *Transplantation, 101*(3), 575–587. *https://doi.org/10.1097/tp.0000000000001539.*

[14] Mohan, S., Chiles, M.C., Patzer, R.E., Pastan, S.O., Husain, S.A., Carpenter, D.J., Dube, G.K., Crew, R.J., Ratner, L.E., & Cohen, D.J. (2018). Factors leading to the discard of deceased donor kidneys in the United States. *Kidney International, 94*(1), 187–198. *https://doi.org/10.1016/j.kint.2018.02.016.*

[15] Moody-Williams, J.D., & Nair, S. (2023, September 15). Organ Transplantation Affinity Group (OTAG): Strengthening accountability, equity, and performance | CMS. *BLOG. https://www.cms.gov/blog/organ-transplantation-affinity-group-otag-strengthening-accountability-equity-and-performance.*

required for the care of transplant patients,'' and a transplant program as ''an organ-specific transplant program within a transplant hospital,'' as so defined. In accordance with 42 CFR 482.98, a transplant program must have a primary transplant surgeon and a transplant physician with the appropriate training and experience to provide transplantation services, who are immediately available to provide transplantation services when an organ is offered for transplantation. The transplant surgeon is responsible for providing surgical services related to transplantation, and the transplant physician is responsible for providing and coordinating transplantation care.

In accordance with CMS' Conditions for Coverage (CfC) for ESRD Facilities at 42 CFR part 494, ESRD facilities are charged with delivering safe and adequate dialysis to ESRD patients, and, among other requirements, informing patients of their treatment modalities, including dialysis and kidney transplantation. The CfCs require ESRD facilities to conduct a patient assessment that includes evaluation of suitability for referral for transplantation, based on criteria developed by the prospective transplantation center and its surgeon(s). General nephrologists refer patients for evaluation for kidney transplants.[16] Candidates for kidney transplant undergo a rigorous evaluation by a transplant program prior to placement on a waitlist, involving evaluation by a multidisciplinary team for conditions pertaining to the potential success of the transplant, the possibility of recurrence, and surgical issues including frailty, obesity, diabetes and other causes of ESRD, infections, malignancies, cardiac disease, pulmonary disease, peripheral arterial disease, neurologic disease, hematologic conditions, and gastrointestinal and liver disease and an immunological assessment; a psychosocial assessment; assessment of adherence behaviors; and tobacco counseling.[17]

Once placed on the waitlist, potential recipients must maintain active status to be eligible to receive a deceased donor transplant.[18] An individual may receive a status of 'inactive' if they are missing lab results, contact information, or any of the other requirements that would be necessary for them to receive an organ transplant if offered. An individual may only receive an organ offer if they have a status of 'active'.[19] Each transplant hospital has its own waitlist, and patients can attempt to be placed on multiple waitlists; OPTN maintains a national transplant waiting list that encompasses the waitlists for all kidney transplant hospitals.[20] [21] Individuals already on dialysis continue to receive regular dialysis treatments while waiting for an organ to become available. After surgery, a transplant nephrologist manages the possible outcomes of organ rejection and infection, and other medical complications.[22]

2. HHS Oversight and Priorities

HRSA, which oversees the OPTN, and CMS play a vital role in protecting the health and safety of Americans as they engage with the U.S. health care system.[23] The OPTN operates a complex network of computerized interactions whereby specific deceased donor organs get matched to individual patients on the national transplant waiting list. The Scientific Registry of Transplant Recipients (SRTR), operated under contract with HRSA, is responsible for providing statistical and analytic support to the OPTN. Section 373 of the PHS Act requires the operation of the SRTR to support ongoing evaluation of the scientific and clinical status of solid organ transplantation.[24]

CMS oversees and evaluates OPO performance. OPOs must meet performance measures and participate in, and abide by certain rules of, the OPTN.[25] The PHS Act requires the Secretary to establish outcome and process performance measures to recertify OPOs (Part H section 371; 42 U.S.C. 273). CMS has promulgated the OPO CfCs at 42 CFR part 486 subpart G.

Additionally, the OPTN Bylaws specify that OPOs whose observed organ yield rates fall below the expected rates by more than a specified threshold would be reviewed by the OPTN Membership Professional Standards Committee (MPSC).[26] CMS also conducts oversight of transplant programs, located within transplant hospitals, which must abide by both the hospital and the transplant program conditions of participation (CoPs). CMS contracts with quality improvement entities such as the ESRD Networks and Quality Improvement Organizations to provide technical support to providers and patients seeking improvements in the transplant ecosystem.

Medicare covers certain transplant-related services when provided at a Medicare-approved facility. Medicare Part A covers the costs associated with a Medicare kidney transplant procedure received in a Medicare-certified hospital and any additional inpatient hospital care needed following the procedure, and organ acquisition costs including kidney registry fees and laboratory tests associated with the evaluation of a Medicare transplant candidate. The evaluation or preparation of a living donor, the living donor's donation of the kidney, and postoperative recovery services directly related to the living donor's kidney donation are covered under Medicare. In addition, deductible and coinsurance requirements do not apply to living donors for services furnished to an individual in connection with the donation of a kidney for transplant surgery. Medicare Part B coverage includes the surgeon's fees for performing the kidney transplant procedure and perioperative care. Medicare Part B also covers physician services for the living kidney donor without regard to whether the service would otherwise be covered by

[16] Virmani, S., & Asch, W.S. (2020). The Role of the General Nephrologist in Evaluating Patients for Kidney Transplantation: Core Curriculum 2020. *American Journal of Kidney Diseases, 76,* 567–579. *https://doi.org/10.1053/j.ajkd.2020.01.001.*

[17] Chadban, S.J., Ahn, C., Axelrod, D.A., Foster, B.J., Kasiske, B.L., Kher, V., Kumar, D., Oberbauer, R., Pascual, J., Pilmore, H.L., Rodrigue, J.R., Segev, D.L., Sheerin, N.S., Tinckam, K.J., Wong, G., & Knoll, G.A. (2020). KDIGO Clinical Practice Guideline on the Evaluation and Management of Candidates for Kidney Transplantation. *Transplantation, 104*(4S1), S11. *https://doi.org/10.1097/TP.0000000000003136.*

[18] National kidney Foundation. (2017, February 10). *The Kidney Transplant Waitlist—What You Need to Know.* National Kidney Foundation. *https://www.kidney.org/atoz/content/transplant-waitlist.*

[19] *The kidney transplant waitlist.* (n.d.). Transplant Living. *https://transplantliving.org/kidney/the-kidney-transplant-waitlist/.*

[20] National kidney Foundation. (2019, June 12). *Understanding the transplant waitlist.* National Kidney Foundation. *https://www.kidney.org/content/understanding-transplant-waitlist.*

[21] National kidney Foundation. (2016, August 4). *Multiple Listing for Kidney Transplant.* National Kidney Foundation. *https://www.kidney.org/atoz/content/multiple-listing.*

[22] *Transplant Nephrology Fellowship.* (n.d.). *Www.hopkinsmedicine.org.* Retrieved May 30, 2023, from *https://www.hopkinsmedicine.org/nephrology/education/transplant_fellowship.html#:~:text=Diagnose%20and%20manage%20acute%20and.*

[23] On March 22, 2023, HRSA announced an initiative that included several actions to strengthen accountability and transparency in the OPTN. These actions include modernization of the OPTN information technology system. HRSA also intends to issue contract solicitations for multiple awards to support the OPTN.

[24] *Mission, Vision, and Values.* (n.d.). *Www.srtr.org. https://www.srtr.org/about-srtr/mission-vision-and-values/.*

[25] U.S. Congress. (1934) United States Code: Social Security Act, 42 U.S.C. 301–Suppl. 4 1934.

[26] Bylaws—OPTN. (n.d.). Optn. *transplant.hrsa.gov.* Retrieved May 30, 2023, from *https://optn.transplant.hrsa.gov/policies-bylaws/bylaws/.*

Medicare. Part A and Part B share responsibility for covering blood, including packed red blood cells, blood components and the cost of processing and receiving blood.

Medicare Part B covers immunosuppressive drugs following an organ transplant for which payment is made under Title XVIII. Immunosuppressive drugs following an organ transplant are covered by Part D when an individual did not have Part A at the time of the transplant. Beneficiaries who have Medicare due to ESRD alone lose Medicare coverage 36 months following a successful kidney transplant. Section 402(a) of the Consolidated Appropriations Act (CAA) of 2021 added section 1836(b) of the Act to provide coverage for immunosuppressive drugs beginning January 1, 2023, for eligible individuals whose eligibility for Medicare based on ESRD ends by reason of section 226A(b)(2) of the Act for those three-years post kidney transplant. Under section 1833 of the Act, the amounts paid by Medicare for immunosuppressive drugs are equal to 80 percent of the applicable payment amount; beneficiaries are thus subject to a 20 percent coinsurance for immunosuppressive drugs covered by both Part B and the Medicare Part B Immunosuppressive Drug Benefit (Part B–ID).

3. Federal Government Initiatives To Enhance Organ Transplantation

a. CMS Regulatory Initiatives To Enhance Organ Transplantation

On September 30, 2019, we published the final rule, ''Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care'' (84 FR 51732). The rulemaking, in part, aimed to address the concern that too many organs are being discarded that could be transplanted successfully, including hearts, lungs, livers, and kidneys. This rule implemented changes to the transplant program regulations, eliminating requirements for re-approval of transplant programs pertaining to data submission, clinical experience, and outcomes. We believed that the removal of these requirements aligned with our goal of increasing access to kidney transplants by increasing the utilization of organs from deceased donors and reducing the organ discard rate (84 FR 51749). We sought improved organ procurement, greater organ utilization, and reduction of burden for transplant hospitals, while still maintaining the importance of safety in the transplant process.

On December 2, 2020, we issued a final rule titled, ''Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations'' (85 FR 77898), which revised the OPO CfCs by replacing the previous outcome measures with new transparent, reliable, and objective outcome measures. In modifying the metrics used for assessing OPO performance, we sought to promote greater utilization of organs that might not otherwise be recovered or used due to perceived organ quality.[27]

While these regulatory changes recently went into effect with the goal of improving the performance of transplant hospitals and OPOs and to promote the procuring of organs and delivering them to prospective transplant recipients, we acknowledged the need for improvements in health, safety, and outcomes across the transplant ecosystem, including in transplant programs, OPOs, and ESRD facilities.[28] [29] In particular, we recognize that further action must be taken to address disparities and inequities observed across transplant hospitals.

We published a request for information in the **Federal Register** on December 3, 2021, titled ''Request for Information: Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Facilities'' (86 FR 68594) (hereafter known as the ''Transplant Ecosystem RFI''). This RFI solicited public comments on potential changes to the requirements that transplant programs, OPOs, and ESRD facilities must meet to participate in the Medicare and Medicaid programs. Specifically, we solicited public comments on ways to:

- Continue to improve systems of care for all patients in need of a transplant;
- Increase the number of organs available for transplant for all solid organ types;
- Encourage the use of dialysis in alternate settings or modalities over in-center hemodialysis where clinically appropriate and advantageous;
- Ensure that the CMS and HHS policies appropriately incentivize the creation and use of future new treatments and technologies; and
- Harmonize requirements across government agencies to facilitate these objectives and improve quality across the organ donation and transplantation ecosystem.

We also solicited information related to opportunities, inefficiencies, and inequities in the transplant ecosystem and what can be done to ensure all segments of our healthcare systems are invested and accountable in ensuring improvements to organ donation and transplantation rates (86 FR 68596). The Transplant Ecosystem RFI focused on questions in the areas of transplantation, kidney health and ESRD facilities, and OPOs. For transplant programs, specific topics included transplant program CoPs, patient rights, and equity in organ transplantation and organ donation (86 FR 68596). For kidney health and ESRD facilities, topics included maintaining and improving health of patients, ways to identify those at risk of developing chronic kidney disease (CKD), improving detection rates of CKD, and ways to close the CKD detection, education, and care health equity gap (86 FR 68599). Other topics included home dialysis, dialysis in alternative settings such as nursing homes and mobile dialysis, and alternate models of care (86 FR 68600). For OPOs, specific topics included assessment and recertification, organ transport and tracking, the donor referral process, organ recovery centers, organ discards, donation after cardiac death, tissue banks, organs for research, and vascular composite organs. (86 FR 68601 through 68606)

The Transplant Ecosystem RFI followed three executive orders addressing health equity that were issued by President Biden on January 20 and January 21, 2021—

- Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (E.O. 13985, 86 FR 7009, January 20, 2021);

[27] The Organ Procurement Organizations Annual Public Aggregated Performance Report for 2023 is available at *https://www.cms.gov/files/document/opo-annual-public-performance-report-2023.pdf.*

[28] One study—Doby, B.L., Ross-Driscoll, K., Shuck, M., Wadsworth, M., Durand, C.M., & Lynch, R.J. (2021). Public discourse and policy change: Absence of harm from increased oversight and transparency in OPO Performance. *American Journal of Transplantation, 21*(8), 2646–2652. *https://doi.org/10.1111/ajt.16527*—showed that deceased donor organ donation increased during 2019, that is., during the period of public debate about regulating OPO performance.

[29] In addition, CMS finalized a policy in the final rule for FY 2023 for the Medicare Physician Fee Schedule that Medicare Part A and Part B payment can be made for dental or oral examinations, including necessary treatment, performed as part of a necessary workup prior to organ transplant surgery. In the final rule, CMS describes certain dental services as inextricably linked and integral to the clinical success of organ transplantation. (87 FR 69671–69675).

• Executive Order on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation (E.O. 13988, 86 FR 7023, January 25, 2021); and

• Executive Order on Ensuring an Equitable Pandemic Response and Recovery (E.O. 13995, 86 FR 7193, January 26, 2021).

The RFI was among several issued by CMS in 2021 to request public comment on ways to advance health equity and reduce disparities in our policies and programs.

CMS's regulatory initiatives since 2018 pertaining to organ donation and transplantation have included final rules modifying CoPs and CfCs for transplant programs (84 FR 51732) and OPOs (85 FR 77898), respectively, and our recent RFI on transplant program CoPs, OPO CfCs, and the ESRD facility CfCs (86 FR 68594). These regulations and RFIs have sought to foster greater health and safety for patients, greater transparency for all patients, increases in organ donation and transplantation, and reduced disparities in organ donation and transplantation. Through these regulations, we are working to attain these goals by designing and implementing policies that improve health for all people affected by the transplant ecosystem.

b. CMS Innovation Center Payment Models

The Innovation Center is currently pursuing complementary alternative payment model tests—the ESRD Treatment Choices (ETC) Model and the Kidney Care Choices (KCC) Model—aimed at enhancing kidney transplantation and improving health-related outcomes for patients with late-stage CKD and ESRD, thereby reducing costs to the Medicare program. The impetus for the ETC and KCC Models originated with evaluation findings for the earlier Comprehensive ESRD Care (CEC) Model, which ran from October 2015 through March 2021, that showed large dialysis organizations achieving positive clinical and financial outcomes relating to services to Medicare beneficiaries receiving dialysis, though the CEC Model did not achieve net savings to Medicare.[30] The CEC Model focused on patients being treated in ESRD facilities, with no explicit incentives to encourage increases in kidney transplantation.

The ETC and KCC Models have engaged a broader range of health care providers beyond ESRD facilities, including nephrology professionals and transplant providers, and address transplantation. Each model includes direct financial incentives for increasing the number of kidney transplants.

The ETC Model, which began January 1, 2021, and which is scheduled to end on June 30, 2027, is a mandatory model that tests whether greater use of home dialysis and kidney transplantation for Medicare beneficiaries with ESRD reduces Medicare expenditures while preserving or enhancing the quality of care furnished to those beneficiaries. We established requirements for the ETC Model in the Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures final rule (85 FR 61114 through 61381). These requirements are codified at 42 CFR subpart C. The ETC Model tests the effects of certain Medicare payment adjustments to participating ESRD facilities and Managing Clinicians (clinicians who manage ESRD beneficiaries and bill the Monthly Capitation Payment (MCP)). The payment adjustments are designed to encourage greater utilization of home dialysis and kidney transplantation, support beneficiary modality choice, reduce Medicare expenditures, and preserve or enhance quality of care. Under the ETC Model, CMS makes upward adjustments to certain payments under the ESRD Prospective Payment System (PPS) to certain dialysis facilities on home dialysis claims, and upward adjustments to the MCP paid to certain Managing Clinicians on home dialysis-related claims (85 FR 61117). In addition, CMS makes upward and downward adjustments to PPS payments to participating ESRD facilities and to the MCP paid to participating Managing Clinicians based on the Participant's home dialysis rate and transplant waitlisting and living donor transplant rate (85 FR 61117). The ETC Model's objectives, as described in the final rule, include supporting paired donations and donor chains, and reducing the likelihood that potentially viable organs are discarded (85 FR 61128). The ETC Model was updated by the final rule dated November 8, 2021, titled ''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'' and the final rule dated November 7, 2022, titled ''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'' (87 FR 67136). We finalized further modifications to the ETC Model related to the availability of administrative review of an ETC Participant's targeted review request in the final rule issued on November 6, 2023, titled ''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'' (88 FR 76345).

CMS is also operating the ETC Learning Collaborative, which is focused on increasing the availability of deceased donor organs for transplantation.[31] The ETC Learning Collaborative regularly convenes ETC Participants, transplant hospitals, OPOs, and large donor hospitals, with the goal of using learning and quality improvement techniques to systematically spread the best practices of the highest performing organizations. CMS is employing quality improvement approaches to improve performance by collecting and analyzing data to identify the highest performers, and to help others to test, adapt and spread the best practices of these high performers throughout the entire national organ recovery system (85 FR 61346).

The KCC Model, which began its performance period on January 1, 2022, and is scheduled to end on December 31, 2026, is a voluntary model that also builds upon the CEC Model structure to encourage health care providers to better manage the care for Medicare beneficiaries with CKD stages 4 and 5 and ESRD, delay the onset of dialysis, and incentivize kidney transplantation. Various entities are participating in the KCC Model, including nephrologists and nephrology practices, dialysis facilities, and other health care providers. The participating entities receive a bonus payment for each aligned beneficiary who receives a

[30] The results of the CMS-sponsored evaluation of the CEC Model are available at *https://innovation.cms.gov/innovation-models/comprehensive-esrd-care.* The 5-year model test reduced Medicare expenses by $217 million, or 1.3 percent relative to the pre-CEC period. These results do not account for shared savings payments to the model participants. There was a 3 percent decrease in the number of hospitalizations and a 0.4 percent increase in the number of outpatient dialysis sessions for Medicare beneficiaries in CEC compared to non-CEC beneficiaries. In addition, the CEC Model improved key quality outcomes.

[31] Centers for Medicare & Medicaid Services. *https://innovation.cms.gov/innovation-models/esrd-treatment-choices-model.*

kidney transplant, so long as the transplant remains successful over a certain time period. CMS plans to continue to evaluate the effectiveness of the ETC and KCC Models in achieving clinical goals, improving quality of care, and reducing Medicare costs.[32]

The IOTA Model proposes to complement the ETC and KCC Models and expand kidney model participation to kidney transplant hospitals, which are a key player in the transplant ecosystem, to test whether two-sided risk payments based on performance increase access to kidney transplants for ESRD patients placed on the waitlists of participating transplant hospitals.

c. HRSA Initiatives Involving Kidney Transplants

NOTA established the OPTN almost 40 years ago to coordinate and operate the nation's organ procurement, allocation, and transplantation system. There are about 400 member organizations that comprise the OPTN. Section 372(b)(2)(A) of the PHS Act charges the OPTN with establishing a national list of individuals who need organs and a national computer system to match organs with individuals on the waitlist. HRSA has also undertaken efforts in alignment with CMS efforts and Federal Government initiatives to improve accountability in OPTN functions. On March 22, 2023, HRSA launched the OPTN Modernization Initiative to strengthen accountability, equity, and performance in the organ donation and transplantation system through a focus on five key areas: technology, data transparency, governance, operations, and quality improvement and innovation.[33] The OPTN Modernization Initiative was further supported by the Securing the U.S. Organ Procurement and Transplantation Network Act (Pub. L. 118–14), which included several key provisions proposed in the President's Fiscal Year 2024 Budget and was signed into law on September 22, 2023.[34] The new law expressly authorizes HHS to make multiple awards to different entities, which could enable the OPTN to benefit from best-in-class vendors and provide a more efficient system that strengthens oversight and improves patient safety.

Effective July 14, 2022, revisions to the OPTN Bylaws were made related to the Transplant Program Performance to establish new criteria for identification of transplant programs that enter MPSC performance review based on the following criteria: [35]

- The transplant program's 90-day post-transplant graft survival hazard ratio is greater than 1.75 during the 2.5-year time period; or
- The transplant program's 1-year post-transplant graft survival conditional on 90-day post-transplant graft survival hazard ratio is greater than 1.75 during a 2.5-year period.

Transplant programs that meet either of the criteria, as reported by the SRTR, must participate in the OPTN Membership and Professional Standards Committee (MPSC) performance review, which may require the member to take appropriate actions to determine if the transplant program has demonstrated sustainable improvement, including, but not limited to—

- Providing information about the program structure, procedures, protocols and quality;
- Review processes;
- Adopting and implementing a plan for improvement;
- Participating in an informal discussion with MPSC members; and
- Participating in a peer visit.

The MPSC would continue to review the transplant program under the performance review until the MPSC determines that the transplant program has made sufficient and sustainable improvements to avoid risk to public health or patient safety. If the MPSC's review determines that a risk to patient health or public safety exists, the MPSC may request that a member inactivate or withdraw a designated transplant program, or a specific component of the program, to mitigate the risk. Transplant programs that do not participate in the MPSC performance review process or fail to act to improve their performance are subject to the policies described in Appendix L of the OPTN Bylaws, Reviews and Actions, including the declaration of ''Member Not in Good Standing.'' While being designated ''Member Not in Good Standing'' does not necessarily lead to the closure or removal of that program from receiving reimbursement from Federal health insurance programs, the Secretary can, based on a recommendation from the OPTN Board of Directors, revoke OPTN membership, close an OPTN member, or remove the ability of the member to receive Federal funding from Medicare or Medicaid. Additionally, numerous private payers align with the MPSC metrics and SRTR star rating system that evaluate transplant hospitals on post-transplant performance to create their Centers of Excellence programs. Therefore, MPSC reviews and performance on the MPSC monitoring measures are a powerful regulatory incentive for transplant programs.

In the final rule, dated September 22, 2020, titled ''Removing Financial Disincentives to Living Organ Donation'' (85 FR 59438), HRSA expanded the scope of qualified reimbursable expenses incurred by living donors under the Living Organ Donation Reimbursement Program to include lost wages and dependent care (childcare and elder care) expenses to further the goal of reducing financial barriers to living organ donation. The program previously only allowed for reimbursement of travel, lodging, meals, and incidental expenses. In the final notice, dated September 22, 2020, titled, ''Reimbursement of Travel and Subsistence Expenses Toward Living Organ Donation Program Eligibility Guidelines,'' HRSA increased the income eligibility threshold under the Living Organ Donation Reimbursement Program from 300 percent to 350 percent of the Federal Poverty Guidelines (85 FR 59531).

3. Rationale for the Proposed IOTA Model

a. Alignment With Federal Government Initiatives and Priorities

For decades, patients and health care providers have confronted an imbalance in the number of transplant candidates and the supply of acceptable donor organs, including kidneys and other organs. Observed variation in access to organ transplantation by geography, race/ethnicity, disability status, and socioeconomic status, as well as the overall performance of the organ transplantation ecosystem, raised the need to make performance improvements and address disparities.[36] Strengthening and improving the

[32] The evaluation report for the first two years (2021, 2022) of the ETC Model is available at *https://www.cms.gov/priorities/innovation/data-reports.*

[33] *HRSA Announces Organ Procurement and Transplantation Network Modernization Initiative | HRSA.* (n.d.). *Www.hrsa.gov.* Retrieved August 20, 2023, from *https://www.hrsa.gov/optn-modernization/march-2023.*

[34] The White House. (2023, September 22). *Bill Signed: H.R. 2544.* The White House. *https://www.whitehouse.gov/briefing-room/legislation/2023/09/22/bill-signed-h-r-2544/#:~:text=On%20Friday%2C%20September%2022%2C%202023,Organ%20Procurement%20and%20Transplantation%20Network.*

[35] OPTN. (n.d.). *Enhance Transplant Program Performance Monitoring System, Phase 1 (July 2022) Sponsoring Committee: Membership and Professional Standards Bylaws Affected.* Retrieved August 20, 2023, from *https://optn.transplant.hrsa.gov/media/hgkksfuu/phase-1_tx-prgm-performance-monitoring_dec-2021.pdf.*

[36] Moody-Williams, J.D., & Nair, S. (2023, December 13). Organ Transplantation Affinity Group (OTAG): Strengthening accountability, equity, and performance | CMS. *BLOG. https://www.cms.gov/blog/organ-transplantation-affinity-group-otag-strengthening-accountability-equity-and-performance.*

performance of the organ transplantation ecosystem is a priority for HHS. To that end, OTAG was established in 2021 by CMS and HRSA and has expanded interagency coordination and collaboration to ''drive improvements in donations, clinical outcomes, system improvement, quality measurement, transparency, and regulatory oversight.'' [37] Collectively, CMS and HRSA seek to—

- Reduce variation of pre-transplant and referral practices; [38]
- Increase availability and use of donated organs;
- Increase accountability for organ procurement and matching;
- Promote equitable access to transplants; and
- Empower patients, families, and caregivers to actively engage in the transplant journey.

We believe the proposed IOTA Model has the potential to substantially increase the number of kidney transplants in a way that enhances fairness for all affected individuals, regardless of socioeconomic status or other factors that limit access to care and negatively affect health outcomes, thereby improving quality of care, reducing costs to Medicare, and prolonging lives. The IOTA Model, as proposed, is complementary to the ETC and KCC Models, and to other CMS and HRSA initiatives, with the collective goal of achieving improvements in processes among transplant hospitals that would spur an increase in both deceased donor and living donor kidney transplantation and reduce population health disparities. Furthermore, although we are targeting our proposals to kidney transplant programs, we seek to test specific modifications for Medicare payment and other programmatic measures that would establish a framework for potential future interventions for transplantation relating to the other solid organ types.

In the following sections of this proposed rule, we review scientific literature that outlines specific ways that kidney transplantation can be enhanced. Although not the focus of our analysis, we also present findings pertaining to the transplantation of other organs, especially livers. We aim to show how the types of interventions that we are proposing might also apply for any future efforts to increase transplant numbers for other organ types, and to continue to pursue the goal of greater equity. We also describe recent efforts from CMS and HRSA to enhance organ transplantation that complement our proposals to use payment incentives as a policy lever to increase the number of kidney transplants and achieve a fairer distribution.

b. End Stage Renal Disease Impact

According to the United States Renal Data System (USRDS), in 2021 about 808,536 people in the United States were living with ESRD, almost double the number in 2001.[39] Prevalence of ESRD varied by Health Service Area (HSA) and ESRD Network.[40] Stratified by age and race/ethnicity, ESRD was consistently more prevalent among older people (65 and older) and in Black people.[41] Diabetes and hypertension are most often the primary cause of ESRD.[42] According to the National Kidney Foundation, these diseases disproportionately affect minority populations, increasing the risk of kidney disease.[43] Year-over-year, incidence of ESRD continues to increase, as the number of patients newly registered increased from 97,856 in 2001 to 134,837 in 2019 and 135,972 in 2021.[44] Studies show that people with kidney transplants live longer than those who remain on dialysis.[45] Despite these positive outcomes, the percentage of prevalent ESRD patients with a functioning kidney transplant remained relatively stable over the past decade, increasing only slightly from 29.7 percent in 2011 to 30.51 percent in 2021.[46] In 2021, 72,864 patients with ESRD were on the kidney transplant waitlist, of which 27,413 were listed during that year.[47] The IOTA Model proposes to focus on the ESRD patients who are on the kidney transplant waitlists of the kidney transplant hospitals that would be required to participate in this Model. ESRD patients represent a small portion of the U.S. population, but the disease burden to the patient and to CMS is great in terms of health outcomes, survival, quality of life, and cost. The ESRD population accounted for 6.1% of total Medicare expenditures in 2020.[48]

Due to wide variability across eligible kidney transplant hospitals, we are unable to estimate the IOTA Model's attributed patient population until the IOTA participants are randomly selected.

c. Benefits of Kidney Transplantation

ESRD, when a person's kidney function has declined to the point of requiring regular dialysis or a transplant for survival, as the person's kidneys are no longer able to perform life-sustaining functions, is the final stage of CKD. ESRD is a uniquely burdensome condition, with uncertain survival and poor quality of life for patients. The higher mortality and substantially greater expenditures and hospitalization rates for ESRD beneficiaries compared to the overall Medicare population suggest the need to explore policy interventions to enhance patients' survival and life experience, as well as to reduce the impact to Medicare. The IOTA Model proposes to improve patient outcomes by incentivizing increased access to kidney transplantation across IOTA participants. Access to this lifesaving treatment may delay or avert dialysis, reduce costs to the Medicare program and to patients, and enhance survival and quality of life.

A kidney transplant involves surgically transplanting a kidney from a living or deceased donor to a kidney transplant recipient. The replacement organ is known as a graft. Most kidneys are transplanted alone, as kidneys transplanted along with other organs are very rare.[49] Fewer than 1,000 patients each year receive a simultaneous kidney-pancreas transplant, which is generally conducted for patients who have kidney failure related to type 1 diabetes mellitus.[50] The kidney in such

[37] Moody-Williams, J.D., & Nair, S. (2023, December 13). Organ Transplantation Affinity Group (OTAG): Strengthening accountability, equity, and performance | CMS. *BLOG. https://www.cms.gov/blog/organ-transplantation-affinity-group-otag-strengthening-accountability-equity-and-performance.*

[38] Pre-transplant/referral practices are inclusive of the referring physician's assessment criteria, patient education, and feedback to the referring physician from the transplant assessment.

[39] United States Renal Data System. 2023.End Stage Renal Disease: Chapter 1. Figure 1.5.

[40] United States Renal Data System. 2023. End Stage Renal Disease: Chapter 1. Figure 1.7.

[41] United States Renal Data System. 2023. End Stage Renal Disease: Chapter 1. Figure 1.8.

[42] United States Renal Data System. 2023. End Stage Renal Disease. Chapter 1. Table 1.3.

[43] National Kidney Foundation. (2016, January 7). *Race, Ethnicity and Kidney Disease.* National Kidney Foundation. *https://www.kidney.org/atoz/content/minorities-KD.*

[44] United States Renal Data System. 2023. End Stage Renal Disease. Chapter 1. Figure 1.1.

[45] National Kidney Foundation. (2017, February 14). *Kidney Transplant.* National Kidney Foundation. *https://www.kidney.org/atoz/content/kidney-transplant.*

[46] United States Renal Data System. 2023. End Stage Renal Disease: Chapter 7. Figure 7.16.

[47] United States Renal Data System. 2023. End Stage Renal Disease: Chapter 7. Figures 7.1 and 7.2.

[48] United States Renal Data System. 2022. End Stage Renal Disease: Chapter 9.

[49] According to OPTN data, in 2022, there were 389 kidney-heart transplants in the U.S, 789 kidney-liver transplants, 22 kidney-lung transplants, and 3 kidney-intestine transplants. See *https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/.*

[50] Health Resources and Services Administration. (2020). Scientific Registry for Transplant Recipients. *OPTN/SRTR 2020 Annual Data Report:*

Continued

a simultaneous transplant may come from a living or deceased donor, but other organs mostly come from a deceased donor.

About three-quarters of kidney transplants in the U.S. are deceased donor kidney transplants.[51] For deceased donor transplantation, a patient needs to contact a transplant hospital and arrange for an evaluation to assess the feasibility of surgery. The patient's name would then be added to a list of individuals who can receive organ offers. This is known as the kidney transplant hospital's kidney transplant waitlist. Living donation occurs when a living person donates an organ to a family member, friend, or other individual. People unknown to one another sometimes take part in paired exchanges, which allow the switching of recipients based on blood type and other biological factors. The numbers of deceased donor kidney donation have increased over the past decade, while living donor kidney donation has remained relatively constant, declining in 2020 with the COVID–19 pandemic.[52]

Kidney transplantation is considered the optimal treatment option for most ESRD patients. Although not a cure for kidney disease, a transplant can help a person live longer and improve quality of life. On average, patients experience 14 to 16 years of function from a kidney from a living kidney donor, while few people survive more than a decade on dialysis.[53] According to one source, the majority of deceased donor kidneys are expected to function for about 9 years, with high quality organs lasting longer.[54] A systematic review of studies worldwide finds significantly lower mortality and risk of cardiovascular events associated with kidney transplantation compared with dialysis.[55] Additionally, this review finds that patients who receive transplants experience a better quality of life than treatment with dialysis.[56] The average dialysis patient is admitted to the hospital nearly twice a year, often as a result of infection, and more than 35 percent of dialysis patients who are discharged are re-hospitalized within 30 days of being discharged.[57] Among transplant recipients, there are lower rates of hospitalizations, emergency department visits, and readmissions compared to those still on dialysis.[58] In general, from the standpoint of long-term survival and quality of life, a living donor kidney transplant is considered the best among all kidney transplant options for most people with CKD.[59] [60]

A cost advantage also arises with kidney transplantation. Per person per year Medicare FFS spending for beneficiaries with ESRD with a transplant is less than half that for either hemodialysis or peritoneal dialysis.[61] While the benefits to patient survival and quality of life from living donor kidney transplantation are more pronounced, a recent literature review shows that deceased donor kidney transplantation generally produced better outcomes at a lower cost compared to dialysis, although old age and a high comorbidity load among kidney transplant patients may mitigate this advantage.[62] An earlier study, based on a single hospital, showed rates of hospitalization, a substantial factor in health care costs, to be lower among kidney transplant patients than for those on dialysis.[63]

Despite these outcomes, in 2020, only about 30 percent of prevalent ESRD patients—those with existing ESRD diagnoses—in the U.S. had a functioning kidney transplant, or graft.[64] In 2016, only 2.8 percent of incident ESRD patients—meaning patients newly diagnosed with ESRD—received a preemptive kidney transplant, allowing them to avoid dialysis.[65] These rates are substantially below those of other developed nations. The U.S. was ranked 17th out of 42 reporting countries in kidney transplants per 1,000 dialysis patients in 2020, with 42 transplants per 1,000 dialysis patients in 2020.[66] We seek to test policy approaches aimed at increasing the number of kidney transplants over current levels given these relatively low numbers and the overall benefit to patients from transplantation, as well as the potential savings to Medicare.

d. Kidney Transplant Rates and Unmet Needs

Annually, more than one hundred thousand individuals in the U.S. begin treatment for ESRD.[67] Despite transplantation being widely regarded as the optimal treatment for people with ESRD, as well as being more cost-effective in the long term compared to dialysis, only a minority of people with ESRD (13 percent) are added to the waitlist, and even fewer receive a transplant. To be added to the kidney transplant waitlist, a patient must complete an evaluation at a transplant hospital, and the patient must be found to be a good candidate for a transplant. Nearly 5,000 patients on the national kidney transplant waiting list die each year.[68] [69] [70] These trends have persisted

Pancreas. https://srtr.transplant.hrsa.gov/annual_reports/2020/Pancreas.aspx.

[51] United States Renal Data System. 2022. USRDS Annual Data Report. Volume 2. End-stage Renal Disease (ESRD) in the United States, Chapter 7: Transplantation. Figure 7.10b.

[52] United States Renal Data System. 2022. USRDS Annual Data Report. Volume 2. End-stage Renal Disease (ESRD) in the United States, Chapter 7: Transplantation. Figure 7.10b.

[53] *Get the Facts on Kidney Transplantation Before You Start Dialysis—Penn Medicine.* (2019, July 24). *Www.pennmedicine.org. https://www.pennmedicine.org/updates/blogs/transplant-update/2019/july/kidney-transplant-facts-before-dialysis.*

[54] Organ Procurement and Transplantation Network. Kidney Donor Profile Index (KDPI) Guide for Clinicians. *https://optn.transplant.hrsa.gov/professionals/by-topic/guidance/kidney-donor-profile-index-kdpi-guide-for-clinicians/#:~:text=Figure%201%20shows%20that%20a,function%20for%20about%209%20years.*

[55] Tonelli, M., Wiebe, N., Knoll, G., Bello, A., Browne, S., Jadhav, D., Klarenbach, S., & Gill, J. (2011). Systematic Review: Kidney Transplantation Compared With Dialysis in Clinically Relevant Outcomes. *American Journal of Transplantation, 11*(10), 2093–2109. *https://doi.org/10.1111/j.1600-6143.2011.03686.x.*

[56] Ibid.

[57] United States Renal Data System. 2022. USRDS Annual Data Report. 2022. Volume 2. End-stage Renal Disease (ESRD) in the United States, Chapter 5: Hospitalization. Figures 5.1a, 5.9.

[58] United States Renal Data System. 2021. USRDS Annual Data Report. Volume 2. End-Stage Renal Disease (ESRD) in the United States. Chapter 5: Hospitalization, Figures 5.1a, 5.6a, 5.8.

[59] Nemati, E., Einollahi, B., Lesan Pezeshki, M., Porfarziani, V., & Fattahi, M.R. (2014). Does Kidney Transplantation With Deceased or Living Donor Affect Graft Survival? *Nephro-Urology Monthly, 6*(4). *https://doi.org/10.5812/numonthly.12182.*

[60] United States Renal Data System. 2022. USRDS Annual Data Report. Volume 2. End-stage Renal Disease (ESRD) in the United States, Chapter 7: Hospitalization. Figure 7.20.b.

[61] United States Renal Data System. 2022. USRDS Annual Report. Volume 2. End-stage Renal Disease (ESRD) in the United States, Chapter 9: Healthcare Expenditures for Persons with ESRD. Figure 9.11.

[62] Fu, R., Sekercioglu, N., Berta, W., & Coyte, P.C. (2020). Cost-effectiveness of Deceased-donor Renal Transplant Versus Dialysis to Treat End-stage Renal Disease. *Transplantation Direct, 6*(2), e522. *https://doi.org/10.1097/txd.0000000000000974.*

[63] Khan, S., Tighiouart, H., Kalra, A., Raman, G., Rohrer, R.J., & Pereira, B.J.G. (2003). Resource utilization among kidney transplant recipients. *Kidney International, 64*(2), 657–664. *https://doi.org/10.1046/j.1523-1755.2003.00102.x.*

[64] United States Renal Data System. 2022 Annual Data Report. Volume 2. End Stage Renal Disease Chapter 7 Transplantation Figure 7.16.

[65] United States Renal Data System. *2018. Annual Data Report. Volume 2. Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. Figure 1.2.* Retrieved from *https://www.usrds.org/2018/view/v2_01.aspx.*

[66] United States Renal Data System. 2022. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 11.17b.

[67] United States Renal Data System. 2022. 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; 2022.Volume 2: End-stage Renal Disease (ESRD) in the United States, Chapter 1: Incidence, Prevalence, Patient Characteristics.

[68] Scientific Registry of Transplant Recipients. Program Specific Reports. *Www.srtr.org.* Retrieved

for several decades despite increases in the number of kidney transplants from deceased donors and living donors.

From 1996 to 2019, the number of kidneys made available for transplantation from deceased donors grew steadily, in part because of organs that became available as a result of the opioid epidemic.[71] [72] In 2018 and 2019, the total number of kidney transplants rose steadily as compared to previous years.[73] In 2019, almost one third of patients received a transplant within one year of being placed on the waitlist (32.9 percent), and the rate reached 51.8 percent within 5 years of being placed on the waitlist.[74] The number of kidney transplants increased by 10.2 percent from 2018 to 2019, but fell by 2.7 percent from 2019 to 2020, from 24,511 to 23,853. The reduction was precipitated by a 23.6 percent decline in living donor transplants on account of the COVID–19 pandemic.[75] The overall number of patients with a functioning graft continued its upward trend, reaching 245,846 in 2020, an increase of 2.7 percent from 2019.[76] Nonetheless, these gains in kidney transplantation in the U.S. have fallen far short of the prevailing need among individuals with ESRD or facing the prospect of kidney failure. The number of individuals with ESRD added to the waitlist for a kidney transplant reached a high of 28,533 in 2019, but dropped slightly to 25,136 in 2020, while rising to 27,413 in 2021.[77] At the end of 2021, 72,864 individuals were on the waitlist for a kidney transplant.[78]

The increase in deceased donor kidney transplantation was accompanied by a gradual but steady decline in the number of living donor transplants as compared to patients undergoing dialysis. The total number of living donor transplants per year has risen moderately over the past two decades, from 5,048 in 2000 to 5,241 in 2020, and 5,971 in 2021.[79] [80] With the overall dialysis population growing, the rate of living donor transplants per 100 patient-years on dialysis declined from 1.4 to 0.8 transplants from 2010 to 2020.[81] A report states the proportion of patients undergoing living donor kidney donation to have decreased from 37 percent in 2010 to 29 percent in 2019.[82] A study in 2013 of OPTN data found that the decline in living donation appeared most prominent among men, Black/African Americans, and younger and lower income adults, potentially leading to longer waiting times for transplantation, greater dialysis exposure, higher death rates on the waitlist, lower graft and patient survival for recipients, and higher overall healthcare costs for the care of patients with ESRD.[83]

e. Disparities

Kidney transplantation research in the U.S. reveals disparities across a number of different axes including geography, race and ethnicity, disability, socioeconomic status, neighborhood factors, and availability of health insurance.[84] [85] [86] [87] [88] Studies during the past decade have shown substantial disparities in kidney transplant rates among transplant programs at a national level, as well as both among and within donation service areas (DSAs).[89] A 2020 study examined data from a registry that included all U.S. adult kidney transplant candidates added to the waitlist in 2011 and 2015, comprising 32,745 and 34,728 individuals, respectively.[90] Among transplant programs nationwide, in 2015, the study found that the probability of a deceased donor transplant within three years for the average patient to be up to 16 times greater in some transplant hospitals as compared to others.[91] Substantial differences in probability of deceased donor transplantation were found even within DSAs, where all transplant programs utilize the same OPO and local organ supply. For the 2015 cohort, there was a median 2.3-fold difference between the highest and lowest hospital in each DSA in the 43 of 58 DSAs with more than one transplant hospital. The largest absolute difference in probability of transplant occurred in a DSA with seven transplant programs, with a patient on the waitlist at the transplant program with the highest probability of

June 15, 2023, from *https://www.srtr.org/reports/program-specific-reports/*.

[69] Too Many Donor Kidneys Are Discarded in U.S. Before Transplantation—Penn Medicine. (2020, December 16). *www.pennmedicine.org. https://www.pennmedicine.org/news/news-releases/2020/december/too-many-donor-kidneys-are-discarded-in-us-before-transplantation.*

[70] United States Renal Data System. 2022 Annual Data Report. Volume 2. End Stage Renal Disease Chapter 7 Transplantation Figure 7.4.

[71] Hariharan, S., Israni, A. K., & Danovitch, G. (2021). Long-Term Survival after Kidney Transplantation. New England Journal of Medicine, 385(8), 729–743. *https://doi.org/10.1056/nejmra2014530.*

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[73] United States Renal Data System. 2021. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.11.

[74] United States Renal Data System. 2021. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.7.

[75] United States Renal Data System. 2022. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.10b.

[76] United States Renal Data System. 2022. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.16.

[77] United States Renal Data System. 2023. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.1.

[78] United States Renal Data System. 2023. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.2.

[79] United States Renal Data System. 2012. Annual Data Report. Atlas ESRD. Table 7.1.

[80] United States Renal Data System. 2023. Annual Data report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.10a.

[81] United States Renal Data System. 2022. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.10a.

[82] Charnow, J.A. (2021, June 8). *Living Donor Kidney Transplants Declined in the Last Decade.* Renal and Urology News. *https://www.renalandurologynews.com/home/conference-highlights/american-transplant-congress/living-donor-kidney-transplantation-decreased-after-2010-united-states-trends/.*

[83] Rodrigue, J.R., Schold, J.D., & Mandelbrot, D.A. (2013). The Decline in Living Kidney Donation in the United States. *Transplantation Journal, 96*(9), 767–773. *https://doi.org/10.1097/tp.0b013e318298fa61.*

[84] King, K.L., Husain, S.A., Schold, J.D., Patzer, R.E., Reese, P.P., Jin, Z., Ratner, L.E., Cohen, D.J., Pastan, S.O., & Mohan, S. (2020). Major Variation across Local Transplant Centers in Probability of Kidney Transplant for Wait-Listed Patients. Journal of the *American Society of Nephrology, 31*(12), 2900–2911. *https://doi.org/10.1681/ASN.2020030335.*

[85] Melanson T., Basu M., Plantiga L., Pastan S., Mohan S., Patzer R. (2017). Variation in Living Donor Kidney Transplantation among U.S. Transplant Centers. *American Journal of Transplantation, 17* (suppl 3).

[86] United States Renal Data System. 2022. Annual Data Report. Supplements: COVID–19, Racial and Ethnic Disparities Figures 14–4 and 14.15.

[87] Wesselman, H., Ford, C.G., Leyva, Y., Li, X., Chang, C.-C.H., Dew, M.A., Kendall, K., Croswell, E., Pleis, J.R., Ng, Y.H., Unruh, M.L., Shapiro, R., & Myaskovsky, L. (2021). Social Determinants of Health and Race Disparities in Kidney Transplant. *Clinical Journal of the American Society of Nephrology, 16*(2), 262–274. *https://doi.org/10.2215/cjn.04860420.*

[88] Ng, Y.-H., Pankratz, V.S., Leyva, Y., Ford, C.G., Pleis, J.R., Kendall, K., Croswell, E., Dew, M.A., Shapiro, R., Switzer, G.E., Unruh, M.L., & Myaskovsky, L. (2019). Does Racial Disparity in Kidney Transplant Wait-listing Persist After Accounting for Social Determinants of Health? *Transplantation,* 1. *https://doi.org/10.1097/tp.0000000000003002.*

[89] With the enactment of NOTA, CMS designated donation service areas (DSAs); generally, each DSA includes an OPO within its geographic area. Until March 2021, when OPTN implemented the current policy for allocation of deceased donor kidneys, the priority for organs acquired by an OPO was based, among other factors, on an individual's residence within the DSA extending around the OPO.

[90] King, K.L., Husain, S.A., Schold, J.D., Patzer, R.E., Reese, P.P., Jin, Z., Ratner, L.E., Cohen, D.J., Pastan, S.O., & Mohan, S. (2020). Major Variation across Local Transplant Centers in Probability of Kidney Transplant for Wait-Listed Patients. Journal of the *American Society of Nephrology, 31*(12), 2900–2911. *https://doi.org/10.1681/ASN.2020030335.*

[91] King et al. 2020. 2903.

transplant being 9.8 times more likely to receive a transplant than a patient at the transplant program with the lowest probability of receiving a transplant.[92] Factors such as local organ supply, the characteristics of individuals on the waitlist of a given transplant program, the size of the waitlist, and the transplant program's volume of transplants may account for the differences observed nationally across DSAs. However, the variation among transplant programs across DSAs is significantly associated with organ offer acceptance patterns at individual transplant hospitals.[93] This underscores the need to address geographic disparities and for more transparency on how transplant programs make decisions on organ offers for their waitlist patients.

Living donor kidney donation also varies widely among transplant hospitals. A 2018 report using OPTN data from 2015 showed that while most transplant hospitals perform few living donor kidney transplants, certain transplant hospitals have substantially higher rates for their waitlist patients than the median rate. Differences among transplant hospitals were correlated with geographic region and the number of deceased donor kidney transplantations performed.[94] This underscores the need for initiatives and processes among transplant hospitals to encourage living donations to reduce geographic disparities.

Disparities in kidney transplantation rates for various populations in the U.S. have long been documented. Literature over the past two decades has focused on Non-Hispanic Black patients, who experience lower rates of deceased and living donor kidney transplantation as compared to Non-Hispanic White patients, while being four times more likely to have kidney failure. Black/African Americans and Hispanics/Latinos with kidney failure experience lower rates of kidney transplantation compared with White patients.[95] Additionally, Black/African Americans and Hispanics/Latinos, along with Asians, American Indian/Alaskan Natives, and other minorities, are at a higher risk of illnesses that may eventually lead to kidney failure, such as diabetes and high blood pressure.[96]

The literature over several decades has also addressed the effect of differences in age, gender, socioeconomic status (SES), and cultural aspects.[97] Recent studies have emphasized poverty and income differentials in analyzing the interplay of these and other factors among populations referred for kidney transplantation at several large transplant hospitals.[98] [99] [100] [101] This research extends in time prior to the Kidney Allocation System (KAS) of 2014, which aimed to lessen the impact of racial differences on access to kidney transplantation.

Research findings support the proposition that a broad interpretation of social determinants of health (SDOH) may substantially explain racial disparities in both deceased and living donor kidney transplantation.[102] Recently, a comprehensive survey of the literature on disparities in transplantation for kidneys and other organs found that socioeconomic factors may substantially explain disproportionately lower transplant rates and longer wait times.[103] As described in recent literature, a person's SDOH may contribute to inequities in their prospects for waitlist registration and receipt of transplantation.[104] [105] [106] SDOH is defined more broadly than socioeconomic status, to include those conditions in the places where people live, learn, work, and play that affect a wide range of health and quality of life risks and outcomes.[107] More specifically, SDOH include variations in employment, neighborhood factors, education, social support systems, and healthcare coverage that impact health outcomes.

Salient among recent analyses are those of a cohort of patients initially referred for evaluation for a kidney transplant at a large urban transplant hospital between 2010 and 2012. These studies showed lower waitlist registration and transplant rates for Black/African Americans, regardless of SDOH. However, after the introduction of the KAS in 2014, racial difference showed weaker associations with rates of waitlist registration and receipt of a deceased donor transplant, when controlling for SDOH.[108] [109] This finding is consistent with reports showing a decrease nationally in differences in rates of deceased donor kidney transplants among White patients as compared to Black/African American patients and Hispanic/Latino patients on dialysis, following the introduction of the KAS.[110] [111] The studies of this patient cohort showed Black/African American race to be associated with a decrease in probability of kidney transplant, while still according influence to clinical, social, demographic and cultural factors. These factors included older age, lower income, public insurance, having more comorbidities, being transplanted pre-KAS, less social support, and less transplant knowledge.[112] Similarly, an earlier study of a population at a single

[92] King et al., 2020. 2903.

[93] King et al. 2020. 2903–2904.

[94] Melanson T., Basu M., Plantiga L., Pastan S., Mohan S., Patzer R. (2017). Variation in Living Donor Kidney Transplantation among U.S. Transplant Centers. *American Journal of Transplantation, 17* (suppl 3).

[95] United States Renal Data System. 2022. Annual Data Report. Supplements: COVID–19, Racial and Ethnic Disparities Figures 14–4 and 14.15.

[96] National Kidney Foundation. (2016, January 7). Race, Ethnicity, & Kidney Disease. National Kidney Foundation. *https://www.kidney.org/atoz/content/minorities-KD#:~:text=Black%20or%20African%20Americans%20are.*

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[98] Patzer, R. Perryman, J. Schrager, J. Pastan, S. Amaral, S. Gazmararian, J. Klein, M. Kutner, N. McClellan, W. 2012. Patzer, R.E., Perryman, J.P., Schrager, J.D., Pastan, S., Amaral, S., Gazmararian, J.A., Klein, M., Kutner, N., & McClellan, W.M. (2012). The Role of Race and Poverty on Steps to Kidney Transplantation in the Southeastern United States. *American Journal of Transplantation, 12*(2), 358–368. *https://doi.org/10.1111/j.1600-6143.2011.03927.x.*

[99] Wesselman, H., Ford, C.G., Leyva, Y., Li, X., Chang, C.-C.H., Dew, M.A., Kendall, K., Croswell, E., Pleis, J.R., Ng, Y.H., Unruh, M.L., Shapiro, R., & Myaskovsky, L. (2021). Social Determinants of Health and Race Disparities in Kidney Transplant. *Clinical Journal of the American Society of Nephrology, 16*(2), 262–274. *https://doi.org/10.2215/cjn.04860420.*

[100] Ng, Y.-H., Pankratz, V.S., Leyva, Y., Ford, C.G., Pleis, J.R., Kendall, K., Croswell, E., Dew, M.A., Shapiro, R., Switzer, G.E., Unruh, M.L., & Myaskovsky, L. (2019). Does Racial Disparity in Kidney Transplant Wait-listing Persist After Accounting for Social Determinants of Health? *Transplantation,* 1. *https://doi.org/10.1097/tp.0000000000003002.*

[101] Schold, J.D., Gregg, J.A., Harman, J.S., Hall, A.G., Patton, P.R., & Meier-Kriesche, H.-U. (2011). Barriers to Evaluation and Wait Listing for Kidney Transplantation. *Clinical Journal of the American Society of Nephrology, 6*(7), 1760–1767. *https://doi.org/10.2215/cjn.08620910.*

[102] Reed, R.D., & Locke, J.E. (2020). Social Determinants of Health: Going Beyond the Basics to Explore Racial Disparities in Kidney Transplantation. Transplantation, 104, 1324–1325. *https://doi.org/10.1097/tp.0000000000003003.*

[103] National Academies of Science, Engineering, and Medicine. 2022. ''Realizing the Promise of Equity in the Organ Transplantation System. National Academies Press. Washington DC. 88–93.

[104] Centers for Disease Control and Prevention. *Social Determinants of Health at CDC.* Retrieved June 13, 2023, from *https://www.cdc.gov/about/sdoh/index.html.*

[105] Wesselman et al., 2021.

[106] Ng et al., 2020.

[107] Centers for Disease Control and Prevention.

[108] Ng Y et al. 2020. 8.

[109] Wesselman et al., 2021. 271.

[110] United States Renal Data System. 2022. Annual Data Report. End Stage Renal Disease Chapter 7 Transplantation. Figures 7.10a, 7.10b.

[111] *OPTN Two Year Analysis shows effects of Kidney Allocation System https://optn.transplant.hrsa.gov/news/two-year-analysis-shows-effects-of-kidney-allocation-system/.*

[112] Wesselman et al. 2021. 267.

transplant hospital found that socioeconomic factors attenuated the association between racial difference and placement on the waitlist for a kidney transplant.[113] This underscores the need to consider initiatives and improvement activities aimed at addressing SDOH for ESRD patients to remove barriers to access to kidney transplantations.

Living donor transplantation has demonstrated the enduring influence of racial disparities, but also the importance of SES and neighborhood factors. The cohort of patients identified previously, initially referred for evaluation at a large urban hospital between 2010 and 2012, showed that for living donor transplantation, Black/African American race and lower income held a stronger association with a lower probability of living donor transplant than for deceased donor donation.[114] These results accord with findings nationwide that White patients are more likely to receive a living donor transplant, followed by Asian and Hispanic/Latino patients. Black/African American patients have had lower rates of living donor transplants than other racial or ethnic groups.[115] Explanations for these differences have included disparate rates of diabetes, obesity, and hypertension observed among minority populations that may contraindicate living donation by a relative; cultural differences in willingness to donate or ask for a living donation; concerns about costs among potential donors; and lack of knowledge about living donor transplantation on the part of patients, their families, and health care providers.[116] [117]

Research over several decades confirms the relation between health care access and SES factors and disparities in living donor kidney transplantation receipt for Black/African American and Hispanic/Latino patients, and, additionally, that these disparities have increased over time.[118] [119] [120] [121] According to one study, between 1995 and 2014, disparities in the receipt of living donor kidney transplantation grew more for Black/African Americans and Hispanics/Latinos: (1) living in poorer (versus wealthier) neighborhoods; (2) without (versus with) a college degree; and (3) with Medicare (versus private insurance).[122] The study suggests that delays in the receipt of kidney care may contribute to reported racial and ethnic differences in the quality and timing of discussions among patients, families, and clinicians about living donor kidney transplantation as a treatment option.[123]

One study also established associations between rates of living donor kidney transplantation for Black/African Americans and transplant hospital characteristics. While recognizing the potential effect of clinical factors, the study found that hospitals with high overall rates of living donor kidney transplantation showed significantly decreased racial disparities. The authors suggest that such high rates reveal commitment to living donor kidney transplantation, possibly shown in better education programs, more formalized procedures to reduce failure to complete transplant evaluations, increased use of medically complex and unrelated donors, and more success in reducing financial barriers to living donor kidney donation.[124] The study also notes that hospitals with higher percentages of Black/African American candidates experience greater racial disparities. The authors surmise that such a high percentage might indicate an urban setting exhibiting greater differences in access to health care between Black/African Americans and other populations.[125]

Studies have also shown discrimination on the basis of disability with regard to organ transplantation, particularly for individuals with intellectual and developmental disabilities, who are often assumed by transplant providers to be unable to manage post-transplantation care requirements.[126] Discrimination occurs even though individuals' disabilities that are not related to the need for an organ transplant generally have little or no impact on the likelihood that the transplant would be successful.[127] The American Society of Transplant Surgeons has recommended that no patient be discriminated against or precluded from transplant listing solely due to the presence of a disability, whether physical or psychological.[128]

CMS has kept these concerns in mind when developing the IOTA Model proposals. The IOTA Model proposes performance-based payments that hold transplant hospitals selected as the IOTA participants financially accountable for improvements in access to both deceased and living donor kidney transplantations. To reduce disparities and promote health equity, CMS is proposing that the IOTA participants would be required to develop and submit a Health Equity Plan to CMS in PYs 2 through 6. This proposed model design feature is aimed at encouraging IOTA participants to reassess their processes and policies around living and deceased donor kidneys and promote investments in performance and quality improvement activities that address barriers to care, including SDOH. The sequence of steps that patients need to undertake to gain access to kidney transplantation is complex, and the challenge posed by this process for potential recipients may be compounded by racial, socioeconomic and neighborhood factors. Thus, we believe that a unified framework of interventions to address the distinct social contexts underlying differences among racial groups in deceased donor kidney transplantation and living donor kidney transplantation may result in the desired outcomes of greater overall kidney transplant numbers and equity.

[113] Schold et al., 2021.

[114] Wesselman et al., 2021. 270.

[115] United States Renal Data System. 2022. Annual Data Report. End Stage Renal Disease Chapter 7 Transplantation Figure 7.10a.

[116] Purnell, T.S., Hall, Y.N., & Boulware, L.E. (2012). Understanding and Overcoming Barriers to Living Kidney Donation Among Racial and Ethnic Minorities in the United States. *Advances in Chronic Kidney Disease, 19*(4), 244–251. *https://doi.org/10.1053/j.ackd.2012.01.008.*

[117] Rodrigue, J.R., Kazley, A.S., Mandelbrot, D.A., Hays, R., LaPointe Rudow, D., & Baliga, P. (2015). Living Donor Kidney Transplantation: Overcoming Disparities in Live Kidney Donation in the US—Recommendations from a Consensus Conference. *Clinical Journal of the American Society of Nephrology, 10*(9), 1687–1695. *https://doi.org/10.2215/cjn.00700115.*

[118] Purnell, T.S., Luo, X., Cooper, L.A., Massie, A.B., Kucirka, L.M., Henderson, M.L., Gordon, E.J., Crews, D.C., Boulware, L.E., & Segev, D.L. (2018). Association of Race and Ethnicity With Live Donor Kidney Transplantation in the United States From 1995 to 2014. *JAMA, 319*(1), 49. *https://doi.org/10.1001/jama.2017.19152.*

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[121] Rodrigue et al. 2015.

[122] Purnell et al. 2015. 58.

[123] Purnell et al. 2015. 59.

[124] Hall et al. 2012. 855.

[125] Hall et al. 2012. 855.

[126] *See, for example.,* Nat'l Council on Disability, Organ Transplants Discrimination against People with Disabilities: Part of the Bioethics and Disability Series (2019), *https://ncd.gov/sites/default/files/NCD_Organ_Transplant_508.pdf.*

[127] *Id.* at 38–40.

[128] Am. Soc'y of Transplant Surgeons, *Statement Concerning Eligibility for Solid Organ Transplant Candidacy* (Feb. 12, 2021), *https://asts.org/advocacy/position-statements.*

f. Post-Transplant Outcomes

While the need for kidney transplants has grown, the rates of patient and graft survival have increased. Between 2001 and 2020, graft survival rates at 1 and 5 years showed an increasing trend.[129] Patient survival at 1 year increased from 97.5 percent in 2001 to 99.2 percent in 2018, but then declined to 98.9 percent in 2019 and 98.4 percent in 2020; patient survival at 5 years rose from 89.8 percent in 2001 to an all-time high of 93.6 percent in 2013, dropping slightly to 93.2 percent in 2016.[130] For living donor kidney transplants, the rate of graft failure at 3 years decreased from 3.0 per 100 person years in 2010 to 2.1 per 100 person years in 2018. The rate of death at 3 years with a functioning graft also decreased from 1.2 to 1.0 per 100 person-years.[131] For deceased donor kidney transplants, the rate of graft failure at 3 years decreased from 2010 (6.3 per 100 patient years) to 2014 (4.9 per 100 patient years), but increased to 5.3 per 100 patient years in 2018. The same pattern was observed for death with a functioning graft, except that the rate in the 2018 cohort (2.8 per 100 patient years) exceeded that of the 2010 cohort (2.6 per 100 patient years).[132]

A study published in the New England Journal of Medicine in 2021 shows the advantage of transplantation using deceased donor organs over long-term dialysis, even with an increasing trend of adverse conditions among recipients and donors. Notably, patient survival improved between the 1990s and the period from 2008 to 2011, despite increases in both (a) recipients' age, body-mass index (BMI), frequency of diabetes, and length of time undergoing dialysis, as well as a higher proportion of recipients with a previous kidney transplant; and (b) donors' age and in the percentage of donations after circulatory death.[133] Early referral of patients for transplants, kidney exchange programs, better diagnostic tools to identify early acute rejection, innovative therapies for countering rejection and infection, and optimization of immunosuppressive medications may be opportunities to enhance kidney graft survival.[134]

g. Non-Acceptance and Discards in Kidney Transplantation

Studies have documented the substantial extent of deceased donor kidney non-utilization in the U.S. relative to other countries (although methods of defining these rates differ among countries), as well as a steady increase in that trend over the past two decades.[135] [136] [137] [138] [139] A study in 2018 described donor-specific factors, such as biopsy findings and donor history, along with an increasing selectivity among transplant hospitals in accepting organs for transplant and inability to locate a recipient as contributing to this increase in non-utilization.[140] Within the context of the COVID–19 pandemic, the non-utilization of deceased donor kidneys in 2020 rose to the highest level up to that time, 21.3 percent, despite the decline in discard of organs from hepatitis C-positive donors.[141] [142] An analysis found that the donor kidney discard rate peaked at 27 percent during the fourth quarter of 2021.[143]

Since 2014, when the KAS went into effect, OPTN has aimed to address the high rate of kidneys going unused. The new kidney allocation system was developed in response to higher than necessary discard rates of kidneys, variability in access to transplants for candidates who are harder to match due to biologic reasons, inequities resulting from the way waiting time was calculated, and a matching system that results in unrealized life years and high re-transplant rates.[144] The KAS also revised the system that matched waitlisted individuals with available organs.[145] As part of the KAS, the Kidney Donor Profile Index (KDPI) was implemented to assess the quality of kidneys procured for kidney transplants. The KDPI is based on a preliminary measurement, the Kidney Donor Risk Index (KDRI), which estimates the relative risk of post-transplant kidney graft failure based on scores for the deceased donor on a set of 10 demographic and clinic characteristics, including age, height, weight, ethnicity, history of hypertension, history of diabetes, cause of death, serum creatinine, hepatitis C virus status, and donation after circulatory death status.[146] This relative risk is determined in relation to the overall distribution of a grouping of these scores across the overall deceased donor population for the previous year. The KDPI transforms the KDRI to a zero-to-100 scale. Lower KDPI scores are associated with greater expected post-transplant longevity, while higher KDPI

[129] United States Renal Data System. 2023. Annual Data Report. Volume 2. End Stage Renal Disease. Transplantation. Figures 7.19a and 7.19b.

[130] United States Renal Data System. 2023. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figures 7.20a and 720.b.

[131] United States Renal Data System. 2023. Annual Data Report. Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 7.21a.

[132] United States Renal Data System. 2023. Annual Data Report Volume 2. End Stage Renal Disease. Chapter 7. Transplantation. Figure 721.b.

[133] Hariharan S, Israni AK, Danovitch G. Long-Term Survival after Kidney Transplantation. N Engl J Med. 2021 Aug 19;385(8):729–743. doi: 10.1056/NEJMra2014530. PMID: 34407344.

[134] Hariharan, S., Israni, A. K., & Danovitch, G. (2021). Long-Term Survival after Kidney Transplantation. *New England Journal of Medicine, 385*(8), 729–743. *https://doi.org/10.1056/nejmra2014530.*

[135] Mohan, S., Chiles, M. C., Patzer, R. E., Pastan, S. O., Husain, S. A., Carpenter, D. J., Dube, G. K., Crew, R. J., Ratner, L. E., & Cohen, D. J. (2018). Factors leading to the discard of deceased donor kidneys in the United States. *Kidney International, 94*(1), 187–198. *https://doi.org/10.1016/j.kint.2018.02.016.*

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[139] Health Resources and Services Administration. OPTN. (2017). *Two year analysis shows effects of kidney transplantation system.* Optn.*transplant.hrsa.gov*. Retrieved May 30, 2023, from *https://optn.transplant.hrsa.gov/news/two-year-analysis-shows-effects-of-kidney-allocation-system/.*

[140] Mohan, Chiles et al. (2018).

[141] Lentine, K. Smith, J. Hart, A. Miller, J. Skeans, M. Larkin, L. Robinson, A. Gauntt, K. Israni, A. Hirose, R. Snyder, J. (2022). OPTN/SRTR 2020 Annual Data Report: Kidney. American Journal of Transplantation 22(Suppl 2) 21–136.

[142] Following upon the introduction of certain anti-viral drugs, transplanting kidneys from donors infected with Hepatitis C has shown promising outcomes in recent studies. See Penn Medicine News ''Penn Researchers Continue to Advance Transplantation of Hepatitis C Virus-infected kidneys into HCV-Negative Recipients'' August 31, 2020 *https://www.pennmedicine.org/news/news-releases/2020/august/penn-researchers-advance-transplantation-hepatitis-c-virus-infected-kidneys-hcv-negative-recipients.*

[143] Cron, D. Husain, S. Adler, J. (2022). The new distance-based kidney allocation system: Implications for patients, transplant centers, and Organ Procurement Organizations. *Current Transplantation Reports, 9*(4), 304. *https://doi.org/10.1007/s40472-022-00384-z.*

[144] OPTN Kidney Transplantation Committee. (n.d.). *The New Kidney Allocation System (KAS) Frequently Asked Questions.* Retrieved December 6, 2023, from *https://optn.transplant.hrsa.gov/media/1235/kas_faqs.pdf.* p. 4.

[145] OPTN. (n.d.) *The New Kidney Allocation System (KAS) Frequently Asked Questions. https://optn.transplant.hrsa.gov/media/1235/kas_faqs.pdf.* p. 4.

[146] OPTN. (n.d.). *The New Kidney Allocation System Frequently Asked Questions. https://optn.transplant.hrsa.gov/media/1235/kas_faqs.pdf.* pp. 8–9.

scores are associated with a worse expected outcome in this regard.[147]

According to these new allocation rules, the KDPI of an available organ was to be assessed, with donor kidneys with low KDPI scores being offered to patients scoring high in terms of expected longevity. New revisions to the KAS also included an individual's time on dialysis prior to waitlisting to assess waiting time used for determining priority for an available organ, and new rules that allowed for greater access for candidates with blood type B to donor kidneys with other blood types.[148]

An OPTN data analysis from 2014 to 2016, the first two years after KAS implementation, showed that despite substantial increases in both deceased kidney donor transplants and deceased kidney donation, the kidney discard rate increased to 19.9 percent in 2016.[149] OPTN linked the discard rates to KDPI scores, with fewer than 3 percent of donor kidneys with KDPI between zero and 20 percent discarded, compared with 60 percent of donor kidneys with KDPI between 86 and 100 percent being discarded.[150]

In March 2021, OPTN finalized a newer allocation policy, which eliminated the use of DSAs and regions from kidney and pancreas donor distribution. These measures were part of a framework announced in 2019 that also applied to heart, lung, and liver donor distribution, with the goal of reducing the importance of geography in patients' access to organs, and, instead, emphasizing medical urgency.[151] [152] The new system instituted a point system with up to 2 points (equal to 2 years on the wait list) for patients listed at transplant hospitals within 250 nautical miles of the donor hospital, and the points decreasing linearly from the donor hospital to the circle perimeter. The more points an individual has, the higher their position on the waitlist and the more likely they are to receive an organ offer. If there is no candidate within the designated radius, the kidney is offered to patients listed at hospitals outside the fixed circle, based on separate proximity points that decrease linearly as the location of a patient approaches 2,500 nautical miles from the donor hospital.[153]

Interested parties within the transplant ecosystem commented that the new policy might further contribute to the increasing rate of donor organ non-acceptance. According to one review, sharing kidneys over a broader geographic region means that OPOs would need to work with transplant hospitals with which there was no prior relationship.[154] Concern was also expressed about increased transportation time and procurement costs, risk associated with air transport, and a greater number of interactions between transplant hospitals and OPOs.[155] [156] [157] One study notes that policymakers would need to assess the extent to which the new kidney allocation policy might affect organ offer acceptance patterns, organ recovery and utilization rates, and wait times both for the transplant hospital and broader geographic areas.[158] Another report cited unpublished SRTR data, saying that preliminary results suggest an increase in transplant rate overall, but a trend toward higher donor kidney discard and increased cold ischemia time.[159] A study at a single transplant hospital showed that the number of organ offers—for livers and kidneys—grew by 140 percent between May 1, 2019, and July 31, 2021, while the number of transplanted organs remained stable, suggesting less efficient allocation of organs after the new change in allocation policy.[160]

A similar study assessing deceased donor kidney discards from 2000 to 2015 found that 17.3 percent of 212,305 procured deceased donor kidneys were discarded, representing a 91.5 percent increase in deceased donor kidney discards during the same time period. The increase in donor kidney discards outpaced the number of organs recovered for transplantation, adversely impacting transplantation rates and waitlist times. Kidneys with higher KDPIs and from donors with more disadvantageous characteristics were more likely to be discarded. The estimated 5-year graft survival for even the lowest quality kidneys substantially exceeds the average 5-year dialysis survival rate, making discard patterns concerning.[161] The study indicates a significant overlap in the quality of discarded and transplanted deceased donor kidneys, and substantial geographical variation in the odds of donor kidney discards, which, as seen previously, would continue to be observed in SRTR data for following years.[162] The study also found patterns that indicate factors beyond organ quality, including biopsy findings, donor history and poor organ function, and inability to locate a kidney donor recipient, may factor into deceased organ acceptance decisions. Other factors may be driving the deceased donor organ discard rates, as the study found that ''discarded organs were more likely to come from older, heavier donors who were Black, female, diabetic, hypertensive, with undesirable social behavior and higher terminal creatinine.'' [163] This finding accords with observed discard patterns from earlier studies whereby recipients of marginal kidneys, in terms of advanced donor age, hypertension, diabetes, or greater cold ischemia time, showed lower mortality and greater survival benefit for many candidates as

[147] OPTN. (n.d.). *The New Kidney Allocation System Frequently Asked Questions . https://optn.transplant.hrsa.gov/media/1235/kas_faqs.pdf.* p. 4.

[148] OPTN. (n.d.). *The New Kidney Allocation System Frequently Asked Questions. https://optn.transplant.hrsa.gov/media/1235/kas_faqs.pdf.* p. 4.

[149] OPTN. (2017, July 9). *Two Year Analysis shows effects of Kidney Allocation System.* Retrieved June 9, 2023, from *https://optn.transplant.hrsa.gov/news/two-year-analysis-shows-effects-of-kidney-allocation-system/.*

[150] OPTN. (2017, July 9). *Two Year Analysis shows effects of Kidney Allocation System.* Retrieved June 9, 2023, from *https://optn.transplant.hrsa.gov/news/two-year-analysis-shows-effects-of-kidney-allocation-system/.*

[151] Potluri, V. S., & Bloom, R. D. (2021). Effect of Policy on Geographic Inequities in Kidney Transplantation. *American Journal of Kidney Diseases, 79*(6), 897–900. *https://doi.org/10.1053/j.ajkd.2021.11.005.*

[152] Penn Medicine. (2021, November 17). Update: Change in Organ Allocation Designed to Increase Equity in US Kidney and Pancreas Transplantation. *Penn Medicine Physician Blog. https://www.pennmedicine.org/updates/blogs/penn-physician-blog/2021/november/change-in-organ-allocation-designed-to-increase-equity-in-us-kidney-and-pancreas-transplantation.*

[153] Potluri, Bloom. (2021). 897–898.

[154] Potluri, Bloom. (2021) 898.

[155] Gentry, S.E., Chow, E.K.H., Wickliffe, C.E., Massie, A.B., Leighton, T., & Segev, D.L. (2014). Impact of broader sharing on the transport time for deceased donor livers. *Liver Transplantation, 20*(10), 1237–1243. *https://doi.org/10.1002/lt.23942.*

[156] Chow, E.M., DiBrito, S.R., Luo, X., Wickliffe, C., Massie, A.B., Locke, J.E., Gentry, S.E., Garonzik-Wang, J., & Segev, D.L. (2018). Long Cold Ischemia Times in Same Hospital Deceased Donor Transplants. *Transplantation, 102*(3), 471–477. *https://doi.org/10.1097/tp.0000000000001957.*

[157] Adler, J.T., Husain, S.A., King, K.L., & Mohan, S. (2021). Greater complexity and monitoring of the new Kidney Allocation System: Implications and unintended consequences of concentric circle kidney allocation on network complexity. *American Journal of Transplantation, 21*(6), 2007–2013. *https://doi.org/10.1111/ajt.16441.*

[158] Adler et al., 2021. 2012.

[159] Cron, D.C., S. Ali Husain, & Adler, J. T. (2022). The New Distance-Based Kidney Allocation System: Implications for Patients, Transplant Centers, and Organ Procurement Organizations. *Current Transplantation Reports, 9*(4), 302–307. *https://doi.org/10.1007/s40472-022-00384-z.*

[160] Reddy, V., Briget da Graca, Martinez, E., Ruiz, R., Asrani, S.K., Testa, G., & Wall, A. (2022). Single-center analysis of organ offers and workload for liver and kidney allocation. *American Journal of Transplantation, 22*(11), 2661–2667. *https://doi.org/10.1111/ajt.17144.*

[161] Mohan, Chiles et al. 2018. p. 192.

[162] Mohan et al. 2018. p. 195.

[163] Mohan et al. 2018. 192.

compared to staying on the transplant wait list.[164] [165] [166]

Research at this time suggests that CMS regulatory requirements and OPTN policies may have been contributing to transplant hospitals growing more selective in choosing organs for their waitlisted patients. A study from 2017 examined OPTN registry data for deceased donors from 1987 to 2015, showing that changes in the donor pool and certain clinical practices explained about 80 percent of the increase in non-utilization of deceased donor kidneys.[167] However, according to the study, the remainder of kidney discards, not accounted for by these factors, suggests that increased risk aversion was leading transplant hospitals to be more selective about the kidneys they accept, regardless of the actual risk profile. Furthermore, increasing reliance on the part of OPTN, CMS, and private insurers on program-specific reports that assessed the performance of transplant hospitals on transplant graft and recipient survival rates might have been contributing to the overall trend of organs going unused.[168]

The finding of high rates of non-use of organs that could potentially be transplanted with positive outcomes has led to closer examination of trends among transplant hospitals in declining the possible use of organs for specific patients. Information on each organ that is recovered by an OPO is shared with the OPTN, which runs the matching system that determines which organ should be offered to which recipient. If an organ is determined to be a good match for a particular patient, then OPTN would offer that organ to the transplant hospital at which the patient is waitlisted on the patient's behalf.[169] A transplant hospital can decline an offer without informing the candidate of the offer or the reason it was declined.[170] A study in 2019 focused on patient outcomes associated with declines in offers of organs by transplant hospitals. Using OPTN data, the study identified a cohort of 280,041 adults on the kidney transplant waitlist (out of 367,405 candidates on the waitlist from 2008 through 2015, the study period) who received one or more offers for a deceased donor kidney during that period. More than 80 percent of deceased donor kidneys were declined on behalf of one or more candidates before being accepted for transplant, and a mean of 10 candidates who previously received an offer died every day during the study period.[171] As reported by transplant hospitals, organ or donor quality concerns accounted for 92.6 percent of all declined offers, whereas 2.6 percent of offers were refused because of patient-related factors, and an even smaller number for logistical limitations or other concerns. While organ or donor quality concerns remained the primary reason for declined offers across all KDPI ranges, the study observed marked State-level variability in the interval between first offer and death or transplant and in the likelihood of dying while having remained on the wait list after receiving an offer.[172]

The methodology and findings of this study are notable since they draw a correlation between the specific patterns among transplant hospitals of organ non-acceptance and the longevity of patients on the wait list. The tendency among certain hospitals to choose to not use kidneys for specific patients is shown apart from the distinct finding of organs going unused and being discarded. The study shows the potential for a similar effect on patient survival from organ offer non-acceptance as for organ non-use. The authors of an earlier study commented that low acceptance rates of organ offers lead to inefficiency, longer ischemia time, unequal access to donated kidneys, and perhaps to higher rates of discarded organs.[173] The findings in the 2019 study of a wide range of organ offer acceptance rates among transplant hospitals nationwide, as well as of the relation between organ offer declines and patient deaths, suggest the need for incentives for transplant hospitals to accept earlier offers for their patients, which, in turn, could reduce cold ischemia time, and, on the whole, increase patient survival.

h. Non-Acceptance and Discards in Transplantation for Other Solid Organ Types

SRTR has also tracked the non-use, or discard rate, of other solid organ types. In 2020, 9.5 percent of livers recovered were not transplanted, with livers from older donors less likely to be transplanted.[174] The discard rate for pancreases was 23.4 percent in 2020; organs from obese donors were highly likely not to be transplanted.[175] The discard rate for hearts in 2020 was one percent, having stayed similar over the previous decade.[176]

Liver transplantation shows survival benefits for individuals with chronic liver disease, but liver transplantation suffers from a severe shortage of donor organs.[177] [178] A study from 2012 shows organ offer non-acceptance on the part of transplant programs to affect mortality for individuals with end-stage liver disease in a similar manner as for ESRD patients. According to the study, most candidates for a liver transplant who died or were removed from the wait list had received at least one organ offer, suggesting that a substantial portion of waitlist mortality results in part from declined organ offers.[179] As we propose for kidney transplantation, understanding and addressing why livers, and possibly other organs, are not chosen for specific patients also has the

[164] Ojo, A.O., Hanson, J.A., Herwig Ulf Meier-Kriesche, Chike Nathan Okechukwu, Wolfe, R.R., Leichtman, A.B., Agodoa, L.Y., Kaplan, B., & Port, F.K. (2001). Survival in Recipients of Marginal Cadaveric Donor Kidneys Compared with Other Recipients and Wait-Listed Transplant Candidates. *Journal of the American Society of Nephrology, 12*(3), 589–597. *https://doi.org/10.1681/asn.v123589.*

[165] Massie, A.B., Luo, X., Chow, E.K.H., Alejo, J.L., Desai, N.M., & Segev, D.L. (2014). Survival Benefit of Primary Deceased Donor Transplantation With High-KDPI Kidneys. *American Journal of Transplantation, 14*(10), 2310–2316. *https://doi.org/10.1111/ajt.12830.*

[166] Cohen, J.B., Eddinger, K.C., Locke, J.E., Forde, K.A., Reese, P.P., & Sawinski, D. (2017). Survival Benefit of Transplantation with a Deceased Diabetic Donor Kidney Compared with Remaining on the Waitlist. *Clinical Journal of the American Society of Nephrology, 12*(6), 974–982. *https://doi.org/10.2215/cjn.10280916.*

[167] Stewart et al. (2017). 575.

[168] Stewart et al. (2017). 585.

[169] National Kidney Foundation. (2017, February 10). *The Kidney Transplant Waitlist—What You Need to Know.* National Kidney Foundation. *https://www.kidney.org/atoz/content/transplant-waitlist.*

[170] Husain, S.A., King, K.L., Pastan, S., Patzer, R.E., Cohen, D.J., Radhakrishnan, J., & Mohan, S. (2019). Association Between Declined Offers of Deceased Donor Kidney Allograft and Outcomes in Kidney Transplant Candidates. *JAMA Network Open, 2*(8), e1910312. *https://doi.org/10.1001/jamanetworkopen.2019.10312.*

[171] Husain et al. 2019.

[172] Husain et al. 2019.

[173] Wolfe, R.A., Laporte, F., Rodgers, A.M., Roys, E., Fant, G., & Leichtman, A.B. (2007). Developing Organ Offer and Acceptance Measures: When ''Good'' Organs Are Turned Down. *American Journal of Transplantation,* 7, 1404–1411. *https://doi.org/10.1111/j.1600-6143.2007.01784.x.*

[174] OPTN/SRTR 2020 Annual Data Report. 2020. Liver. Figures LI 49, 50.

[175] OPTN/SRTR 2021 Annual Data Report. Pancreas. Figures PA 39, 43.

[176] OPTN/SRTR 2021 Annual Data Report. Heart. Figure HR 52.

[177] Merion, R.M., Schaubel, D.E., Dykstra, D.M., Freeman, R.B., Port, F.K., & Wolfe, R.A. (2005). The Survival Benefit of Liver Transplantation. *American Journal of Transplantation, 5*(2), 307–313. *https://doi.org/10.1111/j.1600-6143.2004.00703.x.*

[178] Ross, K., Patzer, R.E., Goldberg, D.S., & Lynch, R.J. (2017). Sociodemographic Determinants of Waitlist and Posttransplant Survival Among End-Stage Liver Disease Patients. *American Journal of Transplantation, 17*(11), 2879–2889. *https://doi.org/10.1111/ajt.14421.*

[179] Lai, J.C., Feng, S., & Roberts, J.P. (2012). An Examination of Liver Offers to Candidates on the Liver Transplant Wait-List. *Gastroenterology, 143*(5), 1261–1265. *https://doi.org/10.1053/j.gastro.2012.07.105.*

potential to lead to improved outcomes and longer lives.

i. Organ Transplant Affinity Group

On September 15, 2023, CMS published a blog post entitled ''Organ Transplantation Affinity Group (OTAG): Strengthening accountability, equity, and performance.'' [180] This blog discussed the formation of OTAG, a Federal collaborative with staff from CMS and HRSA working together to strengthen accountability, equity, and performance to improve access to organ donation, procurement, and transplantation for patients, donors, families and caregivers, and providers. The proposed IOTA Model is a part of this coordinated effort from the OTAG and relies on input from across CMS and HRSA.

C. Provisions of the Proposed Regulation

1. Proposal To Implement the IOTA Model

In this section of the proposed rule, we propose our policies for the IOTA Model, including model-specific definitions and the general framework for implementation of the IOTA Model. The proposed upside risk payment to the IOTA participants and the proposed downside risk payment from IOTA participants to CMS, are designed to increase access to kidney transplants for patients with ESRD on the IOTA participant's waitlist. As described in section I of this proposed rule, access to kidney transplants widely varies by region and across transplant hospitals and disparities by demographic characteristics are pervasive, raising the need to strengthen and improve performance. We theorize that the IOTA Model financial structure would promote improvement activities across selected transplant hospitals that address access barriers, including SDOH, thereby increasing the number of transplants, quality of care, and cost-effective treatment. Selected transplant hospitals may be motivated to revisit processes and policies around deceased and living donor organ acceptance to identify opportunities for improvement. The IOTA model payments may also require selected transplant hospitals to engage in care delivery transformation to better coordinate and manage patient care and needs, invest in infrastructure, improve the patient, family, and caregiver experience, and engage a care delivery team that is tasked with holistic patient care.

a. Proposal for Model Performance Period

We are proposing a 6-year ''model performance period.'' We are proposing to define the model performance period as the 72-month period from the model start date, comprised of 6 individual PYs. During the model performance period, the IOTA participants' performance would be measured and assessed for purposes of determining their performance-based payments, as proposed in this rule. We propose to define the ''performance year'' (PY) as a 12-month calendar year during the model performance period. We are proposing to define the start of the model performance period as the ''model start date,'' and we propose a model start date of January 1, 2025, meaning that PY 1 would be January 1, 2025 to December 31, 2025, and the model performance period would end on December 31, 2030. We are proposing a 6-year model performance period to allow sufficient time for selected transplant hospitals to invest in care delivery transformation and realize returns on investments.

We alternatively considered a 3- or 5-year model performance period; however, we believe that a 3-year model performance period would be too short to allow adequate time for selected transplant hospitals to invest in care delivery transformations. Additionally, our analyses detailed in section III.D. of this proposed rule project that considerable savings to Medicare would be achieved after the fifth PY, which is another reason why we are proposing a 6-year model performance period. We also considered a 10-year model performance period similar to some more recent Innovation Center models; however, given that this would be a mandatory model, we believe it important to limit the duration of the initial test to a shorter period.

We alternatively considered proposing to begin the IOTA Model on April 1, 2025 or July 1, 2025, to allow selected transplant hospitals more time to prepare to implement the model and to better align the model performance periods with that of our data sources, as detailed in section III.C. of this proposed rule. However, we are proposing a January 1, 2025 start date because we believe that there will be sufficient time for IOTA participants to prepare for the model. A proposed start date of January 1st also aligns with other CMS calendar year rules. We propose that in the event the model start date is delayed from the proposed start date, the model performance period for the entire model would be 6 PYs with each PY being a 12-month period that begins on the model start date. For example, if the IOTA Model were to begin April 1, 2025, ''performance year'' would still be defined as a 12-month period beginning on the model start date, meaning April 1, 2025, to March 31, 2026. As a result, the model performance period end date would also shift to include a 72-month period from the model start date In the previous example, the model performance period would be April 1, 2025, to March 31, 2031.

We seek comment on the proposed model performance period of 6 years and the proposed model start date. We also seek comment on the alternative model performance periods that we considered of 3, 5, and 10 years. We also seek comment on the alternative start dates (April 1, 2025, and July 1, 2025), and the subsequent adjustments to the model performance period if the model start date were to change.

b. Other Proposals

We are also proposing additional policies for the IOTA Model, including the following: (1) the method for selecting transplant hospitals for participation; (2) the schedule and methodologies for the performance-based payments, and waivers of certain Medicare payment requirements solely as necessary to test these payment methodologies under the model; (3) the performance assessment methodology for selected transplant hospitals, including the proposed methodologies for patient attribution, target setting and scoring, and calculation of performance across the achievement domain, efficiency domain, and quality domain; (4) monitoring and evaluation; and (5) overlap with other Innovation Center models and CMS programs.

We propose that IOTA participants would be subject to the general provisions for Innovation Center models specified in 42 CFR part 512 subpart A and in 42 CFR part 403 subpart K, effective January 1, 2025. The general provisions at subpart A of part 512 are also the subject of proposed revisions in this proposed rule. As described in section II.B. of this proposed rule, we are proposing to expand the applicability of the general provisions for Innovation Center models to provide a set of standard provisions for Innovation Center models that are applicable more broadly across Innovation Center models. We believe that this approach would promote transparency, efficiency, and clarity in Innovation Center models and avoid the need to restate the provisions in each

[180] Moody-Williams, J, Nair, S. Organ Transplantation Affinity Group (OTAG): Strengthening accountability, equity, and performance. CMS Blog, September 15, 2023. *https://www.cms.gov/blog/organ-transplantation-affinity-group-otag-strengthening-accountability-equity-and-performance.*

model's governing documentation. We believe that applying these provisions to the IOTA Model would promote these purposes.

We seek comment on our proposal to apply the general provisions for Innovation Center models, or the proposed standard provisions for Innovation Center models, to the IOTA Model.

2. Definitions

We propose at § 512.402 to define certain terms for the IOTA Model. We describe these proposed definitions in context throughout section III. of this proposed rule. We propose to codify the definitions and policies of the IOTA Model at 42 CFR part 512 subpart D (proposed §§ 512.400 through 512.460). In addition, we propose that the definitions contained in the general provision related to Innovation Center models at subpart A of part 512, and the revisions to those provisions proposed in this notice of proposed rulemaking, would also apply to the IOTA Model. We seek comment on these proposed definitions for the IOTA Model.

3. IOTA Participants

a. Proposed Participants

We propose to define ''IOTA participant'' as a kidney transplant hospital, as defined at § 512.402, that is required to participate in the IOTA Model pursuant to § 512.412. In addition, we note that the definition of ''model participant'' contained in *42 CFR part 512.110,* as well as the proposed revisions to that definition, would include an IOTA participant.

We propose to define ''transplant hospital'' as a hospital that furnishes organ transplants as defined in 42 CFR 121.2. We propose this definition to align with the definition used by Medicare. We propose to define ''kidney transplant hospital'' as a transplant hospital with a Medicare approved kidney transplant program. Under § 482.70, a transplant program is ''an organ-specific transplant program within a transplant hospital (as defined in this section).'' Kidney transplants are the most common form of transplants, but not all transplant hospitals have a kidney transplant program. As the focus of the IOTA Model is kidney transplants, we propose this definition of kidney transplant hospital to refer specifically to transplant hospitals that perform kidney transplants. We propose to define ''kidney transplant'' as the procedure in which a kidney is surgically transplanted from a living or deceased donor to a transplant recipient, either alone or in conjunction with any other organ(s). As described in section III.B.4.b. of this proposed rule, the vast majority of kidney transplants are performed alone. However, we believe that it is necessary to include in the definition of kidney transplant those kidney transplants that occur in conjunction with other organ transplants to avoid creating a disincentive for multi-organ transplants within the IOTA Model.

Kidney transplant hospitals are the focus of the proposed IOTA Model because they are the entities that furnish kidney transplants to ESRD patients on the waitlist and ultimately decide to accept donor recipients as transplant candidates. Kidney transplant hospitals play a key role in managing transplant waitlists and patient, family, and caregiver readiness. They are also responsible for the coordination and planning of kidney transplantation with the OPO and donor facilities, staffing and preparation for kidney transplantation, and oversight of post-transplant patient care, and they are largely responsible for managing the living donation process. The proposed model is intended to promote improvement activities across selected transplant hospitals that reduce access barriers, including SDOH, thereby increasing the number of transplants, quality of care, and cost-effective treatment. The IOTA Model would also aim to improve quality of care for ESRD patients on the waitlist pre-transplant, during transplant, and during post-transplant care. As described in section III.B.4.e. of this proposed rule, kidney transplant access and acceptance rates vary nationally across kidney transplant hospitals by geography and other demographic and socioeconomic factors. The Innovation Center has implemented models targeting dialysis facilities and nephrology providers, including in the CEC, ETC, and KCC Models. CMS has also implemented changes to the OPO CfCs to strengthen performance accountability for OPOs. However, kidney transplant hospitals have not been the principal focus of any Innovation Center models to date. Expanding accountability to kidney transplant hospitals, key players in the transplantation ecosystem for ESRD patients, aligns with the larger efforts across CMS and HRSA to improve performance and address disparities in kidney transplantation.

We alternatively considered having the IOTA participants be accountable care organizations (ACOs), such as a kidney transplant ACOs, instead of individual kidney transplant hospitals. In this alternative conception, a kidney transplant ACO would form as a separate legal entity, potentially including kidney transplant hospitals, OPOs, transplant surgeons, and other provider types. The kidney transplant ACO would assume accountability for the number of kidney transplants, equity in the distribution of transplants, and the quality of transplant services from the point of a patient being waitlisted to after a transplant recipient's condition stabilizes following transplantation. This alternative would potentially carry some advantages in the potential for improved coordination among individual providers and suppliers in the kidney transplant ACO, but we believe that it would be administratively burdensome, as it would require the formation of an ACO governing board distinct from the governing boards of individual providers. In addition, such an ACO arrangement possibly would be subject to additional Federal, State, and tribal laws with respect to grievance, licensure, solvency, and other regulations, as well as considerable overlap with other ACO-based Innovation Center models. We therefore believe that the ''IOTA participant'' should be defined as a kidney transplant hospital, as defined at § 512.402, that is required to participate in the IOTA Model pursuant to § 512.412.

We further alternatively considered requiring OPO participation in the IOTA Model as the entity charged with identifying eligible donors and securing organs from deceased donors. However, in 2020, CMS issued a final rule that updated OPO CfC requirements to receive Medicare and Medicaid payment. This final rule focuses on holding OPOs in the transplant ecosystem accountable for improving performance, and the Innovation Center does not plan further interventions regarding OPOs at this time.

We seek public comment on the proposal that the IOTA Model participants would be kidney transplant hospitals.

b. Proposed Mandatory Participation

We propose that all kidney transplant hospitals that meet the eligibility requirements as discussed in section III.C.3.c. of this proposed rule, and that are selected through the participation selection process discussed in section III.C.3.d. of this proposed rule, must participate in the IOTA Model. We believe that a mandatory model is necessary to ensure that a sufficient number of kidney transplant hospitals participate in the IOTA Model such that CMS will be able to conduct a sound evaluation of the model's effects on cost and quality of care in accordance with

section 1115A(b)(4) of the Act. A mandatory model would also minimize the potential for selection bias, thereby ensuring that the model participants are a representative sample of kidney transplant hospitals. We believe a mandatory model is necessary to obtain relevant information about the effects of the model's proposed policies on Medicare savings, kidney transplant volume, kidney transplant acceptance rates, health equity, and quality of care.

Nationally, kidney transplant hospitals serve diverse patient populations, operate in varied organizational and market contexts, and differ in size, staffing, and capability. There is also wide variation across kidney transplant hospitals on performance on kidney transplant access and organ offer acceptance rate ratios by geography and other demographic and socioeconomic factors. We believe that selection bias would be a challenge in a voluntary model because we are proposing that the IOTA Model would include financial accountability on performance on access to kidney transplants and quality of care, and downside risk for poor performers. A mandatory model would address these selection bias concerns and ensure that our model reaches ESRD patients residing in underserved communities.

We alternatively considered making participation in the IOTA Model voluntary. However, we would be concerned that a voluntary model would not be evaluable, would result in insufficient numbers of kidney transplant hospital participants, and would not be representative of kidney transplant hospitals and ESRD patients nationally. These concerns reflect our expectation that the proposed payment approach would disproportionately attract kidney transplant hospitals already performing well in kidney transplant volume, organ offer acceptance rate ratios, and quality of care pre- and post-transplantation. Kidney transplant hospitals already positioned to score high in the IOTA Model's achievement, efficiency, and quality domains may be more likely to join the model than other kidney transplant hospitals, as they would expect to receive upside risk payments. This may be especially true for kidney transplant hospitals that would stand the most to benefit from a model that rewards an increase in the number of kidney transplants. We believe that selection bias in a voluntary model would also limit our ability to assess systematic differences in the IOTA Model's effects on kidney transplant disparities, and may further widen disparity gaps for underserved communities that stand to lose if the model does not reach them. We therefore propose that the IOTA Model would be mandatory for all eligible kidney transplant hospitals selected for participation in the model, as we believe this would minimize the risk of potential distortions in the model's effects on outcomes resulting from hospital self-selection.

We seek public comment on our proposal to make participation in the IOTA Model mandatory.

c. Participant Eligibility

We are proposing kidney transplant hospital participant eligibility criteria that would increase the likelihood that: (1) individual kidney transplant hospitals selected as IOTA participants represent a diverse array of capabilities across the performance domains as discussed in section III.C.5. of this proposed rule; and (2) the results of the model test would be statistically valid, reliable, and generalizable to kidney transplant hospitals nationwide should the model test be successful and considered for expansion under section 1115A(c) of the Act.

We are proposing that eligible kidney transplant hospitals would be those that: (1) performed 11 or more transplants for patients aged 18 years or older annually, regardless of payer type, each of the baseline years (the ''low volume threshold''); and (2) furnished more than 50 percent of its kidney transplants annually to patients over the age of 18 during each of the baseline years. We propose to define ''baseline year'' as a 12-month period within a 3-year historical baseline period that begins 48 months (or 4 years) before the start of each model PY and ends 12 months (or 1 year) before the start of each model PY. For example, if the IOTA Model were to start on January 1, 2025, the baseline years for PY 1 would be the 12-month period that begins January 1, 2021, and ends on December 31, 2023. We propose to define ''non-pediatric facility'' as a kidney transplant hospital that furnishes over 50 percent of their kidney transplants annually to patients 18 years of age or older. CMS would select approximately half of all DSAs nationwide using a stratified sampling methodology, and all eligible kidney transplant hospitals in the selected DSAs would be required to participate in the IOTA Model.

The proposed low volume threshold of 11 or more kidney transplants for ESRD patients aged 18 years or older during each of the three baseline years (as described in section I.B.2.b. of this proposed rule) would exclude low volume kidney transplant hospitals from the IOTA Model. We believe that these kidney transplant hospitals should be excluded from the model because they may not have the capacity to comply with the model's policies, and because the inclusion of this group of kidney transplant hospitals in the model would be unlikely to significantly alter the overall rates of kidney transplantation. We are also proposing a low volume threshold of 11 adult kidney transplants because it is consistent with the minimum thresholds for the display of CMS data to protect the confidentiality of Medicare and Medicaid beneficiaries by avoiding the release of information that can be used to identify individual beneficiaries. We alternatively considered using a higher threshold, such as 30 adult kidney transplants or 50 adult kidney transplants during each of the three baseline years. However, we have found that many kidney transplant hospitals consistently perform between 11 and 50 transplants per year. We further believe that using a higher threshold would decrease the number, size and location of kidney transplant hospitals eligible to be selected for participation in the IOTA Model, thereby limiting the generalizability of the model test. We also recognize that the number of kidney transplants performed by a kidney transplant hospital may fluctuate from year to year, and looking back three years would help determine if a kidney transplant hospital has the capacity to consistently perform 11 or more transplants per year. We seek feedback on this approach for determining which kidney transplant hospitals would be eligible for selection under the model.

We considered including pediatric kidney transplant hospitals as eligible participants in the IOTA Model. However, pediatric kidney transplantation has significantly different characteristics, considerations, and processes from adult kidney transplantation. The number of pediatric kidney transplants performed each year is also exceedingly small, which would present difficulties in reliably determining the effects to the model in the pediatric population. Additionally, a much larger proportion of pediatric kidney transplants are living donor transplants than in the adult population. As such, we do not believe the proposed IOTA Model would function in the same way for both kidney transplant hospitals serving primarily adults and those serving primarily children, and we believe it is necessary to include only non-pediatric

kidney transplant hospitals in the IOTA Model.

We seek comment on our proposed participant eligibility criteria for kidney transplant hospitals, including the requirement that a kidney transplant hospital perform 11 or more kidney transplants annually on patients aged 18 years or older during the baseline years. We also seek comment on the proposal to include only kidney transplant hospitals that meet the proposed definition for a non-pediatric facility during the baseline years.

d. Participant Selection

(1) Overview and Process for Participant Selection

We propose to select eligible kidney transplant hospitals for participation in the IOTA Model using a stratified sampling of approximately half of all DSAs nationwide. All kidney transplant hospitals that meet the proposed participant eligibility criteria described in section III.C.3.c. of this proposed rule and are located in the selected DSAs would be required to participate in the IOTA Model. As defined in *42 CFR 486.302,* a ''Donation Service Area (DSA)'' means a geographical area of sufficient size to ensure maximum effectiveness in the procurement and equitable distribution of organs and that either includes an entire metropolitan statistical area (MSA) or does not include any part of such an area and that meets the standards of subpart G. A DSA is designated by CMS, is served by one OPO, contains one or more transplant hospitals, and one or more donor hospitals. There are currently 56 DSAs as of January 1, 2024. A map of the DSAs can be found on the SRTR website.[181] CMS would use the list of DSAs as it appears on January 1, 2024 to select the DSAs, and therefore the eligible kidney transplant hospitals that would be required to participate in the IOTA Model.

We propose this approach for selecting IOTA participants to obtain a group of eligible kidney transplant hospitals that is representative of kidney transplant hospitals from across the country in terms of geography and kidney transplant volume. We propose to stratify the DSAs into groups based on each DSA's Census Division and the total number of adult kidney transplants performed annually across all eligible kidney transplant hospitals in each DSA during the baseline years for the first PY. Selecting eligible kidney transplant hospitals from these groups of DSAs would ensure that the IOTA participants are representative of eligible kidney transplant hospitals from across the nation in terms of geography and the volume of adult kidney transplants.

A second aim of our proposal to select eligible kidney transplant hospitals from stratified groups of DSAs is to prevent distortions on the effects of the model's policies and features on outcomes. Our analysis of kidney transplant hospital data shows that selecting only some eligible kidney transplant hospitals within a selected DSA to participate in the IOTA Model may shift the supply of deceased donor organs from non-IOTA participants to IOTA participants within the same DSA. The resulting distortions would make it difficult to attribute changes in outcomes to the model and would limit its evaluability.

Our proposed approach for selecting IOTA participants would involve stratifying DSAs into groups based on the average number of adult kidney transplants performed by all eligible transplant hospitals located in the DSA during the baseline years of PY 1. We propose using this variable to stratify the DSAs into groups because increasing the total number of adult kidney transplants is the primary metric that we propose to use to evaluate the IOTA participants' performance in the model.

The proposed approach for IOTA participant selection is as follows:

- Assign all DSAs to a Census Division.[182] The Census Bureau subdivides the United States into four Census Regions (Northeast, Midwest, South, and West) which are in turn divided into nine Census Divisions. CMS would assign each DSA to a single Census Division. Due to the New England region being both a DSA and a Census Division, CMS would combine the Middle Atlantic and New England Census Divisions for a total of eight Census Divisions. If CMS were to keep the New England Census Division separate, the New England DSA would be guaranteed participation in the model in subsequent steps. As such, we are proposing to combine the Middle Atlantic and New England Census Divisions for the purposes of this selection methodology. Some DSAs may span several Census Divisions, but most DSAs will be assigned to the Census Division where the majority of the DSA's population resides according to the 2020 Census data. Puerto Rico is the only DSA which exists outside of a Census Division. This DSA would be assigned to the South Atlantic Census Division as it is the closest geographically. This step would create eight Census Division groups, one for each Census Division (with the exception of the combined Middle Atlantic and New England Census Divisions, which would be grouped together to create one Census Division group).
- Determine the kidney transplant hospitals located within each DSA. CMS would list out the kidney transplant hospitals located within each DSA and assigned Census Division group.
- Identify the eligible kidney transplant hospitals located within each DSA. CMS would use the criteria noted in section III.C.3.c. of this proposed rule to identify the eligible kidney transplant hospitals within each DSA. This step is expected to yield approximately 180 to 200 eligible kidney transplant hospitals total across the eight Census Division Groups.
- For each DSA, determine the average number of adult kidney transplants performed annually across all eligible kidney transplant hospitals during the baseline years for PY 1. CMS would use data from the baseline years for PY 1 (2021–2023) to determine the average number of adult kidney transplants performed annually across all of the eligible transplant hospitals located in each DSA. CMS would sum the number of adult kidney transplants performed by all of the eligible kidney transplant hospitals in a DSA during each of the baseline years for PY 1 and divide each DSA's sum by three to determine the average number of adult kidney transplants furnished annually during the baseline years by the eligible kidney transplant hospitals located within each DSA.
- Within each Census Division group, create two mutually exclusive groups of DSAs using the average number of adult kidney transplants performed annually across the baseline years for PY 1. CMS would separate DSAs assigned to a Census Division group into two mutually exclusive groups of DSAs based on the average number of adult kidney transplants performed annually across the baseline years for PY 1. The two groups within each Census Division group would be: (1) DSAs having higher numbers of adult kidney transplants across the baseline years; and (2) DSAs having lower numbers of adult kidney transplants across the baseline years. Since the average number of adult kidney transplants will be different across each DSA, each Census Division group will have a different cut off to create these two groups. To ensure each DSA has a 50 percent chance of being chosen in step 7, each DSA group

[181] *https://www.srtr.org/reports/opo-specific-reports/interactive-report.*

[182] A complete list of DSAs in the United States as of 2022–2023 can be obtained using the data reporting tool found on the SRTR website (*https://optn.transplant.hrsa.gov/data/view-data-reports/build-advanced/*).

within a Census Division group should have the same number of DSAs. However, in the event of an odd number of DSAs within a Census Division group, CMS would proceed to step six.

- For groups within a Census Division group that contain an odd number of DSAs, CMS would randomly select one DSA from the group. Each of these individual selected DSAs would have a 50 percent probability of being selected for the IOTA Model. For groups within a Census Division group that contain an odd number of DSAs, CMS would randomly select one DSA from the group and determine that individual DSA's chance of selection for inclusion in the IOTA Model with 50 percent probability. Following this step, each group within a Census Division group would have an even number of DSAs.
- Randomly select 50 percent of remaining DSAs in each group. CMS would then take a random sample, without replacement, of 50 percent of the remaining DSAs in each group (the groups being DSAs having higher numbers of adult kidney transplants across the baseline years and DSAs having lower numbers of adult kidney transplants across the baseline years) within each Census Division group. All of the eligible transplant hospitals located within the selected DSAs would be required to participate in the IOTA Model.

We propose that CMS would notify IOTA participants of their selection to participate in the IOTA Model in a form and manner chosen by CMS, such as public notice and email, at least 3 months prior to the start of the model performance period. As described in section III.C.3.b. of this proposed rule, we are proposing that participation in the IOTA Model would be mandatory. As such, if an IOTA eligible transplant hospital is located within one of the DSAs that CMS randomly selects for the IOTA Model, the eligible kidney transplant hospital would not be able to decline participation in this model, nor would it be able to terminate its participation in the model once selected. Model termination policies are further discussed in section III.C.16. of this proposed rule.

(2) Consideration of Alternatives to Proposed Participant Selection Approach

We considered using other geographic units for stratified random sampling to choose IOTA participants, such as Core Based Statistical Areas (CBSAs), Metropolitan Statistical Areas (MSAs), Hospital Referral Regions (HRRs), or States. CBSAs, MSAs, HRRs, and States are commonly known geographic units, and have been used as part of participant selection for other Innovation Center models. We believe selecting participants by DSA significantly mitigates behavior that would artificially inflate the model's effects on kidney transplant volume for the reasons described in the preceding section. OPOs associated with selected DSAs would be expected to benefit from consistency in rules across most or all of their transplant hospitals. The Innovation Center found that selecting participants by DSA improved the ability to detect changes in kidney transplant volume to a level consistent with the anticipated change in kidney transplant volume associated with the model's payment rules. Participants from the same DSA are, for the most part, subject to similar levels of kidney supply, and, with the exception of kidneys from another DSA, the same rules for kidney allocation apply. While OPTN recently updated its organ allocation methodology to allow organs to go outside of the DSA in which an organ was procured, many kidney transplant hospitals still receive a plurality of kidneys from the local OPO in their DSA, ensuring that this is still a meaningful method to group kidney transplant hospitals. Using alternative geographic units would negate these advantages.

We also considered other random sampling techniques, including simple random sampling of transplant hospitals, simple random sampling of DSAs, and cluster sampling of DSAs. Simple random sampling of hospitals risks oversampling regions of the country where transplant hospitals are concentrated and under sampling areas with fewer eligible transplant hospitals. Using simple random sampling of DSAs may result in an unrepresentative sample of DSAs with a greater risk of oversampling regions where DSAs cover small geographic areas. We considered cluster random sampling where half of all DSAs would be sampled in a first step and half of eligible kidney transplant hospitals within selected DSAs would be sampled. However, because this approach would retain half of eligible kidney transplant hospitals in selected DSAs, we expect the model's effects on kidney transplant volume would be overstated because kidney supply flowing towards non-participant hospitals prior to the start of the model would be redirected towards IOTA participants. In addition, CMS's analyses of these alternative sampling approaches indicated the model would not be evaluable because these approaches were associated with lower precision in detecting changes in kidney transplant volumes due to the model compared to the increase in transplant volume anticipated from the model's payment rules.

As an alternative we also considered other variables to create DSA groups for stratified sampling of DSAs. Specifically, after assigning each DSA to a Census Division, we considered stratifying DSAs using the following DSA level variables:

- Number of eligible transplant hospitals in DSA.
- Annual adult kidney transplants per eligible transplant hospital in DSA.
- Average organ/offer acceptance rate ratio across eligible kidney transplant hospitals in DSA.
- Average percent of Medicare kidney transplant recipients dually eligible for Medicare and Medicaid or who are LIS recipients.
- Percent of eligible transplant hospitals in DSA participating in the Kidney Care Choices or ESRD Treatment Choices Models.
- Average percent of kidney transplants from a living donor among eligible kidney transplant hospitals in DSA.

These variables were given consideration in the stratified selection approach because their use would create groups of DSAs whose eligible transplant hospitals are more similar to each other on the listed characteristics instead of only adult kidney transplant volume and Census Division. However, we opted to use the simpler stratified participant selection approach to provide greater transparency in the model's participant selection approach.

We also considered stratified random sampling of individual kidney transplant hospitals using similar variables as those described in the preceding paragraph. Although this approach provided representativeness of sampled transplant hospitals along dimensions important for the model, it would be expected to result in a subset of eligible kidney transplant hospitals in at least a portion of DSAs being designated as participants. As we have described previously, we expect that allowing a portion of DSA kidney transplant hospitals to be model participants would result in an overstatement of the model's effects on kidney transplant volume and other outcomes of interest. As with the sampling approaches considered in the preceding paragraph, CMS's analyses indicated the IOTA Model would not be evaluable if stratified sampling of individual kidney transplant hospitals were used in participant selection for the reasons described previously.

CMS expects that no additional participant selections would be made for the IOTA Model after its start date unless 10 percent or more of selected participants are terminated from the model during the model performance period. If this were to occur, we would address the selection of new participants in future rulemaking.

We seek comment on our proposed approach for selecting IOTA participants and on the alternative approaches considered, including perceived advantages and disadvantages of our proposed participant selection approach relative to alternatives.

4. Patient Population and Attribution

a. Proposed Attributed Patient Population

We propose that the following patients who are alive at the time CMS conducts attribution would be attributed to an IOTA participant: (1) A kidney transplant waitlist patient, as defined in section III.C.4.a. of this proposed rule, regardless of payer type and waitlist status, who is alive, 18 years of age or older, and is registered on a waitlist, as defined in section III.C.4.a. of this proposed rule, to one or more IOTA participants, as identified by the OPTN computer match program (''IOTA waitlist patient,''); and (2) A kidney transplant patient who receives a kidney transplant at the age of 18 years or older from an IOTA participant at any time during the model performance period (''IOTA transplant patient''). These patients would be referred to as IOTA waitlist patients and IOTA transplant patients, respectively, for purposes of assessing each IOTA participant's performance across the achievement domain, efficiency domain, and quality domain as discussed in section III.C.5. of this proposed rule. IOTA waitlist patients and IOTA transplant patients would factor into the model's performance-based payments to IOTA participants.

For the purpose of this model, we propose to define ''waitlist'' as a list of transplant candidates, as defined in 42 CFR 121.2, registered to the waiting list, as defined in § 121.2, and maintained by a transplant hospital in accordance with 42 CFR 482.94(b). We propose to define ''kidney transplant waitlist patient'' as a patient who is a transplant candidate, as defined in § 121.2, and who is registered to a waitlist for a kidney at one or more kidney transplant hospitals.

We understand that many patients on the waiting list are registered at multiple transplant hospitals. Therefore, we propose attributing each of these waitlisted patients to every IOTA participant where they are registered on a waitlist during a given month in the applicable quarter. However, ''kidney transplant patient,'' defined as a patient who is a transplant candidate, as defined in § 121.2, and received a kidney transplant furnished by a kidney transplant hospital, regardless of payer type, would be attributed to the IOTA participant that furnished the kidney transplant.

We propose attributing kidney transplant waitlist patients and kidney transplant recipients to IOTA participants for two reasons. First, we believe that by attributing these patients to IOTA participants it would ensure the full population of potential and actual kidney transplant candidates is represented when measuring participant performance. The waiting list captures most candidates except some living donor recipients. Transplant recipients include those who received deceased or living donor transplants. Second, because CMS is proposing to hold IOTA participants accountable for furnishing kidney organ transplants; focusing on kidney transplant waitlist patients and kidney transplant patients, and attributing them to IOTA participants, aligns with the model's goals of improving access to, and quality of, kidney transplantation, including post-transplant.

CMS is proposing to determine an IOTA participant's performance across the achievement domain, efficiency domain, and quality domain based on all IOTA waitlist patients and IOTA transplant patients, regardless of payer type, as described in section III.C.5. of this proposed rule. That is, an IOTA participant's performance in terms of both Medicare beneficiaries and non-Medicare patients would be used to determine whether the IOTA participant would receive an upside risk payment from CMS, or owe a downside risk payment to CMS. As described in section III.C.5. of this proposed rule, demand for kidney transplants far exceeds supply, raising concerns that if the IOTA Model were limited to Medicare beneficiaries only, the model may inadvertently incentivize inappropriate diversion of donor organs to Medicare beneficiaries to improve their performance in the model, thereby limiting access to non-Medicare beneficiaries and potentially disincentivizing pre-emptive kidney transplants for patients not already covered by Medicare because their CKD has not progressed to ESRD. We believe that the change in care patterns that IOTA participants may undertake to be successful in the IOTA Model are unlikely to apply solely to Medicare beneficiaries under their care.

We considered limiting IOTA waitlist patients and IOTA transplant patients to Medicare beneficiaries only, as Medicare covers more than 50 percent of all kidney transplants from both deceased and living donors. However, we believe it is necessary to include all patients, regardless of payer type, in the IOTA participant's performance calculations to protect against unintended consequences and problematic financial incentives. Moreover, the group of eligible waitlist and transplant patients that would be attributed to each IOTA participant is already relatively small, both in terms of transplant candidates and transplant recipients. Limiting the IOTA Model performance assessment, as described in section III.C.5. of this proposed rule, to Medicare beneficiaries would further limit the patient sample size, potentially affecting our ability to detect changes in performance due to model payments. Therefore, we are proposing that the IOTA Model reflect both Medicare beneficiaries and non-Medicare patients for performance assessment, with Medicare beneficiaries just being a subset of the patient population attributed to each model participant.

We seek public comment on our proposals to include: (1) all kidney transplant waitlist patients, regardless of payer type and waitlist status, who are alive, 18 years of age or older, and registered on a waitlist to an IOTA participant, as identified by the OPTN computer match program; and (2) all kidney transplant patients who receive a kidney transplant, at 18 years of age or older, from an IOTA participant at any time during the model performance period, in each IOTA participant's population of attributed patients. We also seek public comment on our proposal to attribute IOTA waitlist patients and IOTA transplant patients, respectively, to IOTA participants for the purposes of assessing each IOTA participant's performance across the achievement domain, efficiency domain, and quality domain, and to determine performance-based payments to and from IOTA participants.

b. Patient Attribution Process

As described in section III.C.4.a. of this proposed rule, we propose to define ''attribution'' as the process by which CMS identifies patients for whom each IOTA participant is accountable during the model performance period. CMS would identify and assign a set of Medicare and non-Medicare patients to the IOTA participant through attribution. We propose to define

''attributed patient'' as an IOTA waitlist patient or an IOTA transplant patient, as described in section III.C.4.a. of this proposed rule. We propose that a patient may not opt out of attribution to an IOTA participant under the model.

Section III.C.4.b.(1). of this proposed rule outlines in more detail the attribution criteria to identify attributable kidney transplant waitlist patients and kidney transplant patients during initial attribution, quarterly attribution, and at annual attribution reconciliation using Medicare claims data, Medicare administrative data, and OPTN data. In advance of the model start date, we propose to attribute patients to IOTA participants through an initial attribution process described in section III.C.4.b.(2). of this proposed rule; quarterly attribution would be conducted thereafter to update the patient attribution list as described in section III.C.4.b.(3). of this proposed rule, to include the dates in which patient attribution changes occur. After the fourth quarter of each PY, we propose to finalize each IOTA participant's annual attribution reconciliation list for that PY, including removing certain attributed patients, as described in section III.C.4.b(4) of this proposed rule. We propose that once a patient is attributed to an IOTA participant, that attributed patient would remain attributed to the IOTA participant for the duration of the model, unless the patient is removed from the IOTA participant's list of attributed patients during the annual attribution reconciliation process, as described in section III.C.4.b.(4). of this proposed rule.

We also considered proposing that once a patient is attributed to an IOTA participant, either through the initial attribution process or through quarterly attribution, that the patient would remain attributed only through the end of the PY. Initial attribution would then occur prior to the beginning of each PY. However, we choose to align with the attribution processes of our other kidney models to simplify operations.

We propose to identify kidney waitlist patients and kidney transplant patients using SRTR data, OPTN data, Medicare claims data, and Medicare administrative data.

We seek comment on our patient attribution process proposals and alternatives considered.

(1) Attribution and De-attribution Criteria

(i) IOTA Waitlist Patient Attribution

We propose that kidney transplant waitlist patients would be attributed as IOTA waitlist patients to one or more IOTA participants based on where the patient is registered on a kidney transplant waitlist, regardless of payer type and waitlist status, as identified by the OPTN computer match program. We propose that CMS would conduct attribution on a quarterly basis, before each quarter of the model performance period. CMS is proposing to attribute a kidney transplant waitlist patient as an IOTA waitlist patient to an IOTA participant if the patient meets all of the following criteria:

- The patient is registered to one or more IOTA participant's kidney transplant waitlist during a month in the applicable quarter.
- The patient is 18 years or older at the time of attribution.
- The patient is alive at the time of attribution.

For purposes of attributing IOTA waitlist patients to IOTA participants, the proposed criteria must be met on the date that CMS runs attribution, as described in section III.C.4.b.(1).(i). of this proposed rule.

As described in section III.C.4.b.(1). of this proposed rule, a kidney transplant waitlist patient may be registered to more than one waitlist, which is why we propose to attribute kidney transplant waitlist patients as IOTA waitlist patients to IOTA participants in a way that accurately reflects their waitlist registrations. A kidney transplant hospital should be actively engaged in coordinating the transplant process for kidney transplant waitlist patients on their waitlist, as they are responsible for accepting donor organs and furnishing transplants. As such, if a kidney transplant waitlist patient is registered on the waitlist of multiple IOTA participants, CMS would attribute that kidney transplant waitlist patient as an IOTA waitlist patient to all of the IOTA participants that have the kidney transplant waitlist patient on their waitlists.

We alternatively considered limiting IOTA waitlist patient attribution to only one IOTA participant based on ''active'' waitlist status. That is, the IOTA waitlist patient would be attributed to each IOTA participant where the patient is registered to a kidney transplant waitlist with an ''active'' status in a given quarter. A kidney transplant hospital designates patients on its waitlist with an ''active'' status to signal their readiness to receive a donor kidney offer when one becomes available. However, we anticipate that there would be operational challenges if CMS were to base patient attribution on waitlist ''active'' status, as doing so would require real-time and accurate information regarding each patient's waitlist status. There may be a time delay when changing a waitlist status from provisionally inactive to active once minor issues have been resolved. A kidney transplant waitlist patient may be made inactive or ineligible to receive an organ offer if, for example, they have an incomplete transplant evaluation to assess medical readiness, their BMI exceeds the transplant hospital's established threshold, due to infection or patient choice, or because of complications presented by other medical issues. Additionally, due to our inability to recognize differences in the contributions between kidney transplant hospitals in maintaining a patient's transplant readiness, we believe attributing kidney transplant waitlist patients as IOTA waitlist patients to all the IOTA participants where a kidney transplant waitlist patient is registered is the most appropriate approach to IOTA waitlist patient attribution, regardless of waitlist status.

As indicated in section III.C.3.c. of this proposed rule, we are only proposing to include non-pediatric facilities as eligible participants in the IOTA Model. In alignment with this proposal, we propose to exclude pediatric patients under 18 years of age from the population of attributed patients. According to national data from the OPTN, children under the age of 18 make up a small proportion of the kidney transplant candidates registered on the waiting list. However, pediatric patients have greater access to both deceased and living donor kidney transplant relative to adults and are more likely to receive a kidney transplant than adults over the age of 18. Pediatric patients under 18 years of age are also more likely to receive a living donor transplant than adults over the age of 18, and are infrequently the recipient of organs at high risk for non-use.[183] Thus, CMS is not proposing to include pediatric patients under the age of 18 as part of the population that would be identified and attributed to IOTA participants. We alternatively considered including pediatric patients under the age of 18 in the IOTA model patient population, but believe focusing on adults, given their unique challenges

[183] Lentine, K. L., Smith, J. M., Miller, J. M., Bradbrook, K., Larkin, L., Weiss, S., Handarova, D. K., Temple, K., Israni, A. K., & Snyder, J. J. (2023). OPTN/SRTR 2021 Annual Data Report: Kidney. American journal of transplantation: official journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 23(2 Suppl 1), S21–S120. *https://doi.org/10.1016/j.ajt.2023.02.004.*

accessing kidney transplants, is a priority.

The waiting list often has a delay between when a patient's waitlist status changes and when that change is reflected in the data. For example, patients who have died are ineligible for transplant and must be removed from the waiting list, but there may be a time delay between a patient's death and their removal. Thus, we are proposing to limit IOTA waitlist patient attribution to patients who are alive at the time of attribution.

We seek comments on our proposed criteria for identifying and attributing kidney transplant waitlist patients to one or more IOTA participants and alternatives considered.

(ii) IOTA Transplant Patient Attribution

We propose that kidney transplant patients would be attributed as IOTA transplant patients to the IOTA participant that furnished a kidney transplant during the model performance period, if they meet the following criteria:

- The patient was 18 years of age or older at the time of their transplant; and
- The patient was alive at the time of attribution.

We note that an IOTA transplant patient who experiences transplant failure and is then de-attributed from an IOTA participant, as described in section III.C.4.b.(1).(iii). of this proposed rule, could become attributed to an IOTA participant again at any point during the model performance period if they rejoined a kidney transplant waitlist for, or received a kidney transplant from, any IOTA participant and satisfied all of the criteria for attribution as described in section III.C.4.b.(1).(i). or section III.C.4.b.(1).(ii). of this proposed rule.

We propose to attribute kidney transplant patients to the IOTA participant that furnished the transplant to hold the IOTA participant accountable for patient transplant and post-transplant outcomes. We alternatively considered attributing kidney transplant patients based on the plurality of post-transplant services, as identified in Medicare claims, because it would still result in attributing kidney transplant patients to only one IOTA participant and would base attribution on where the majority of services were furnished. We recognize that patients may choose to receive their pre-and post-transplant care from multiple IOTA participants in addition to the IOTA participant that performed their kidney transplant. However, the model's incentives do not support shifting accountability for post-transplant outcomes away from the IOTA participant that furnished the transplant. We believe that the IOTA participant that performed the transplant should remain accountable for any surgery related outcomes, both successes and failures.

We propose not to attribute patients who are younger than 18 years of age at the time of their kidney transplant or who are deceased at the time of attribution due to the same reasons described in section III.C.4.b.(1).(i). of this proposed rule.

We seek comments on our proposed criteria for identifying and attributing kidney transplant patients as IOTA transplant patients to the IOTA participant that furnished their kidney transplant during the model performance period. We also seek comment on the alternative considered.

(iii) De-Attribution Criteria

We propose that CMS would only de-attribute attributed patients from an IOTA participant during annual attribution reconciliation, as described in section III.C.4.b.(4). of this proposed rule. We propose that CMS would de-attribute any attributed patient from an IOTA participant that meets any of the following criteria as of the last day of the PY being reconciled, in accordance with the annual attribution reconciliation list as described in section III.C.4.c. of this proposed rule:

- The IOTA waitlist patient was not registered on an IOTA participant's kidney transplant waitlist on the last day of the PY being reconciled.
- The IOTA waitlist patient died at any point during the PY. We propose that an IOTA waitlist patient who has died during the PY would be removed from the list of attributed IOTA waitlist patients effective on the last day of the PY that the death occurred.
- The IOTA transplant patient has died at any point during the PY. We propose that an IOTA transplant patient who has died during the PY would be de-attributed from the list of attributed IOTA transplant patients effective on the last day of the PY that the death occurred.
- The IOTA transplant patient's kidney failed during the PY, and the patient is not included on the IOTA participant's waitlist. We propose that an IOTA transplant patient who experiences transplant failure at any point during the PY and does not rejoin an IOTA participant's kidney transplant waitlist or receive another transplant from an IOTA participant before the last day of the same PY would be listed as de-attributed in the annual attribution reconciliation list. This IOTA transplant patient would no longer be attributed to the IOTA participant effective the last day of the PY in which the IOTA transplant patient's kidney transplant has failed.

We seek comment on our proposed methodology and criteria for identifying and de-attributing attributed patients from an IOTA participant.

(2) Initial Attribution

We propose that before the model start date, CMS would conduct an ''initial attribution'' to identify and prospectively attribute waitlist patients to an IOTA participant pursuant to § 512.414. The list of IOTA waitlist patients identified through initial attribution, namely the initial attribution list, would prospectively apply to the first quarter of PY 1, effective on the model start date. The purpose of this initial attribution list would be to prospectively provide IOTA participants with a list of their IOTA waitlist patients for the upcoming quarter.

We considered attributing patients to IOTA participants at different points in time, such as the day that a kidney transplant waitlist patient was added to the IOTA participant's kidney transplant waitlist, or the day that a kidney transplant patient received their kidney transplant. This approach would be more precise than considering all attributed patients to be attributed as of the start of the quarter. However, due to the limitations of data sources and the frequency with which these data are updated, we did not see this as a viable alternative.

We seek comment on our proposal to conduct initial attribution before the model start date and alternatives considered.

(3) Quarterly Attribution

We propose that CMS would attribute patients to IOTA participants in advance of each quarter, after initial attribution, and distribute a ''quarterly attribution list'' to each IOTA participant that includes all their attributed patients, including newly attributed patients, on a quarterly basis throughout the model performance period, except in the event of termination as described in section III.C.16.(b). of this proposed rule.

We considered monthly attribution for more frequent updates to the initial attribution list, but believe it would be operationally burdensome. We also considered annual attribution for less frequent updates to the initial attribution list, which would be less operationally burdensome than monthly or quarterly attribution. Annual

attribution is common in other Innovation Center models and CMS programs where the participant is managing total cost of care for a population. The benefits of annual attribution would include prospectively providing participants a stable list of patients for whom they would be held accountable, and, as the process would occur only once a year, would be associated with lower administrative burden. The downside of annual attribution, however, is that IOTA participants would have less frequent updates and understanding of their attributed population, potentially making it hard to plan and budget accordingly. We do not believe annual attribution would be appropriate for the IOTA Model's goal of improving access to kidney transplants and quality of care for a patient population that changes frequently. For example, kidney transplant hospitals add patients to their kidney transplant waitlist throughout the year. Were we to limit attribution to once a year, kidney transplant waitlist patients added during the year would not be attributed to an IOTA participant until the following year, delaying our ability to meet the minimum number of patients required to evaluate a model test. As such, we believe more frequent attribution would be necessary.

We seek comment on our proposal to conduct attribution on a quarterly basis during the model performance period and on the alternatives considered.

(4) Annual Attribution Reconciliation

We propose that after the end of each PY, CMS would conduct annual attribution reconciliation. We propose to define ''annual attribution reconciliation'' as the yearly process by which CMS would: (1) create each IOTA participant's final list of attributed patients for the PY being reconciled by retrospectively de-attributing from each IOTA participant any attributed patients that satisfied a criterion for de-attribution pursuant to § 512.414(c); and (2) create a final list of each IOTA participant's attributed patients who would remain attributed for the PY being reconciled, subject to the attribution criteria in § 512.414(b)(1) and (2). For the purposes of this model, we propose to define ''annual attribution reconciliation list'' as the final cumulative record of attributed patients that would be generated annually for whom each IOTA participant was accountable for during the applicable PY.

For example, after PY 1, CMS would rerun attribution for the entire PY to finalize the list of attributed patients that met the criteria specified in sections III.C.4.b.(1). and (2). of this proposed rule. Once the fourth quarter is complete, CMS would use the fourth quarter attribution list to determine and de-attribute any attributed patients that meet a criterion for de-attribution, as described in section II.C.4.b.(1).(iii). of this proposed rule, from the IOTA participant, as described in section III.C.4.b.(1).(iii). of this proposed rule, and remove those attributed patients from the quarterly attribution list to create the annual attribution reconciliation list. Before the second quarter of the following PY, CMS would distribute the annual attribution reconciliation list to IOTA participants. We propose that these lists, at a minimum, would identify each attributed patient, identify reasons for de-attribution in the previous PY, and the dates in which attribution began, changed, or ended, where applicable.

We seek comment on our proposal to conduct annual attribution reconciliation.

c. IOTA Patient Attribution Lists

We propose that no later than 15 days prior to the start of the first model performance period, CMS would provide the IOTA participant the ''initial attribution list.'' For the purposes of the model, we propose to define ''days'' as calendar days, as defined in 42 CFR 512.110, unless otherwise specified by CMS. On a quarterly basis thereafter, CMS would provide the IOTA participant the ''quarterly attribution list'' no later than 15 days prior to the start of the next quarter. The annual attribution reconciliation list for a given PY would be provided to the IOTA participants after the conclusion of the PY, before the second quarter of the following PY.

We propose that the initial, quarterly, and annual attribution reconciliation lists would be provided in a form and manner determined by CMS.

We seek comment on our proposed attribution list policies.

5. Performance Assessment

a. Goals and Proposed Data Sources

As described in section III.B. of this proposed rule, CMS and the OPTN each have roles in assessing the performance of kidney transplant hospitals. CMS' regulations in 42 CFR part 482 subpart E require certain conditions of participation for kidney transplant hospitals to receive approval to perform Medicare transplant services. Under 42 CFR part 121, the OPTN is required to implement a peer review process by which OPOs and transplant hospitals are periodically reviewed for compliance with the bylaws of the OPTN and the OPTN final rule (63 FR 16332). The OPTN MPSC is charged with performing these evaluations; including the identification of threats to patient safety and public health.[184]

CMS and the OPTN have each acknowledged the limitations of transplant hospital performance assessment based on the one-year patient and transplant survival measure alone. In 2018, CMS eliminated its assessment of one year patient and transplant survival for the purposes of transplant hospital re-approval in the final rule, ''Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care'' (84 FR 51732), leaving assessment of the one year patient and transplant survival measure only for initial Medicare approval, due to concerns that the measure was causing conservative behavior in transplant hospitals.[185] In 2021, the OPTN disseminated a proposal to enhance the MPSC's performance monitoring process by expanding the number of measures used to identify transplant hospital underperformance.[186] In that proposal, the OPTN acknowledged the potential for transplant hospital risk aversion due to the MPSC's evaluations of performance based on the one year patient and transplant survival metric alone and proposed transplant hospital assessment based on a holistic set of measures encompassing aspects of care across the transplant journey.[187]

Strengthening and improving the performance of the organ transplantation system is a priority for HHS, including CMS and HRSA. In accordance with this priority and joint efforts with HRSA, the IOTA Model would aim to improve performance and equity in kidney transplantation by testing whether performance-based payments to IOTA participants increases access to kidney transplants for kidney transplant waitlist and kidney transplant patients attributed to

[184] *https://optn.transplant.hrsa.gov/about/committees/membership-professional-standards-committee-mpsc/.*

[185] Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction. **Federal Register**. *https://www.federalregister.gov/d/2018-19599/p-215.*

[186] *https://optn.transplant.hrsa.gov/media/4777/transplant_program_performance_monitoring_public_comment_aug2021.pdf.*

[187] *Ibid.*

IOTA participants in the model, thereby reducing Medicare program expenditures while preserving or enhancing quality of care. For the IOTA Model, we are proposing a broader set of metrics which aligns with the trends that we believe would encourage IOTA participants to meet the model goals as described in section III.A of this proposed rule.

The IOTA Model would assess performance on a broad set of metrics that were selected to align with all of the following model goals:

- Increase number of, and access to, kidney transplants.
- Improve utilization of available deceased donor organs.
- Support more donors through the living donation process.
- Improve quality of care and equity.

We propose using Medicare claims and administrative data about beneficiaries, providers, suppliers, and data from the OPTN, which contains comprehensive information about transplants that occur nationally, to measure IOTA participant performance in the three model domains: (1) achievement domain; (2) efficiency domain; and (3) quality domain. Medicare administrative data refers to non-claims data that Medicare uses as part of regular operations. This includes information about beneficiaries, such as enrollment information, eligibility information, and demographic information. Medicare administrative data also refers to information about Medicare-enrolled providers and suppliers, including Medicare enrollment and eligibility information, practice and facility information, and Medicare billing information.

We solicit comment on our proposal for selecting performance metrics and performance domains. We also solicit comment on our proposed use of Medicare claims data, Medicare administrative data, and OPTN data to calculate the performance across the three proposed domains, as described in section III.C.5. of this proposed rule.

b. Method and Scoring Overview

In accordance with our proposed goals of the IOTA performance assessment, as described in section III.C.5.a. of this proposed rule, we propose to assess performance across three domains: (1) achievement domain; (2) efficiency domain; and (3) quality domain. We propose to use one or more metrics within each domain to assess IOTA participant performance. We propose that CMS would assign each set of metrics within a domain a maximum point value, with the total possible points awarded to an IOTA participant being 100 points. We propose to define ''final performance score'' as the sum total of the scores earned by the IOTA participant across the achievement domain, efficiency domain, and quality domain for a given PY. We also propose that the combined sum of total possible points would determine whether and how the IOTA Model performance-based payments, as described in section III.C.6.c. of this proposed rule, would apply and be calculated. We propose the following point allocations for each of these three domains:

- The achievement domain would make up 60 of 100 maximum points. The achievement domain would measure the number of kidney transplants performed relative to a participant-specific target, as described in section III.C.5.c. of this proposed rule. The achievement domain would represent a large portion (60 percent) of the maximum total performance score. We weighted the achievement domain performance score more than the efficiency and quality domain because we believe it aligns with the primary goal of the IOTA Model, to increase the overall number of kidney transplants. Additionally, because increasing the number of kidney transplants performed is the primary goal of the model, we believe weighing performance on this measure more than the efficiency domain and quality domain is necessary to directly incentivize participants to meet their target.
- The efficiency domain would make up 20 of 100 maximum points. The efficiency domain would measure performance on a kidney organ offer acceptance rate ratio.
- The quality domain would make up 20 of 100 maximum points. As described in section III.C.5.e. of this proposed rule, the quality domain would measure performance on a set of quality metrics, including post-transplant outcomes, and on three proposed quality measures—CollaboRATE Shared Decision-Making Score, Colorectal Cancer Screening, and 3-Item Care Transition Measure.

We believe that many prospective IOTA participants may already be familiar with the approach of assigning points up to a maximum in multiple domains. This structure is similar to other CMS programs, including the Merit-based Incentive Payment System (MIPS) track of the Quality Payment Program. For MIPS, we assess the performance of MIPS eligible clinicians (as defined in 42 CFR 414.1305) across four performance categories—one of which is quality—and then determine a positive, neutral, or negative MIPS payment adjustment factor that applies to the clinician's Medicare Part B payments for professional services. Similar to MIPS, we are proposing that the IOTA Model would use a performance scoring scale from zero to 100 points across performance domains, and apply a specific weight for each domain. We believe using wider scales of 0 to 100 points would allow us to calculate more granular performance scores for IOTA participants and provide greater differentiation between IOTA participants' performance. In the future, we believe this methodology for assessing performance could be applied with minimal adaptation to future IOTA participants if CMS adds other types of organs transplants to the model through rulemaking. We believe that the approach of awarding points in the achievement, efficiency, and quality domains for a score out of 100 points represents the best combination of flexibility and comparability that would allow us to assess participant performance in the IOTA Model.

The proposed performance domains and scoring structure would also allow us to combine more possible metric types within a single framework. We believe that this approach allows for more pathways to success than performance measurement based on relative or absolute quintiles, which were also alternatively considered, as it would reward efforts made towards achievable targets.

We considered more than three domains to assess performance, which would potentially offer IOTA participants more opportunity to succeed due to the ability to maximize points in different combinations of domains. The more domains there are, the more the maximum points possible in each domain are spread out. However, we limited the number of domains to three to ensure the model is focused and goal-oriented, thus promoting, encouraging, and driving improvement activity and care delivery transformation across IOTA participants that evidence suggest may help achieve desired outcomes. Desired outcomes include delaying or avoiding dialysis, improving access to kidney transplantation by reducing barriers and disparities, reducing unnecessary deceased donor discards, increasing living donors, and improving care coordination and quality of care pre and post transplantation. We believe that the three domains and the proposed performance scoring structure would offer IOTA participants multiple paths to succeed in the proposed IOTA Model due to the ability to maximize points in different combinations of domains.

We also considered not using the three performance domains and scoring structure, instead opting for alternative methods. We considered a performance assessment methodology in which an IOTA participant's performance on a metric would be divided by an expected value for each metric, which would indicate whether an IOTA participant is performing better or worse on a given measure than expected. We would then calculate a weighted average of all performance scores to reach a final score. However, we believe that setting appropriate targets of expected performance for each IOTA participant for each metric would be unrealistic to implement. The additional methodological complexity necessary for this approach would be difficult for an IOTA participant to incorporate into its operations and data systems, thereby limiting an IOTA participant's ability to understand the care practice changes it would need to make to succeed in the IOTA Model.

We also considered assessing IOTA participant performance solely on magnitude of increased transplants over expected transplants. Under this approach, an IOTA participant's number of transplants furnished in a given PY subtracted from expected transplants would show a numeric net gain or loss in total transplants. This net value would be multiplied by an IOTA participant's kidney transplant survival rate to generate a total score for each IOTA participant. This option would reward successfully completed transplants. This methodology reflects the goals of the IOTA Model and acknowledges that kidney transplant failures are an undesirable outcome. In addition, the methodology is simple to evaluate and understand, requiring only two inputs and a simple calculation. However, this approach does not account for efficiency and quality domain metrics, as proposed in section III.C.5.d. and e. of this proposed rule, which we believe to be important goals of the model. Thus, we are not proposing this method to assess IOTA participant performance.

We also considered directly translating the benefits of a kidney transplant by measuring the net effect of increased transplants and post-transplant care at the IOTA participant level. In a performance scoring methodology focused on the net effect of increased transplants and post-transplant care, the number of kidney transplants performed in a given PY would be compared to a benchmark year for the IOTA participant. Each additional kidney transplant would then be multiplied by the expected number of years of dialysis treatment the transplant averted, based on organ quality. Post-transplant care would analyze observed versus expected kidney transplant failures. For IOTA participants that achieved fewer kidney transplant failures than expected, the difference in volumes would be translated into life-years. Each marginal additional year of averted dialysis care would be used to determine the performance-based payment. Because calculating expected transplant failures is a complicated calculation with assumptions based on organ quality, donor age, and donor health conditions, a scoring system of this type would require us to make multiple broad assumptions about individual transplants or average scores across all transplants performed by the IOTA participant to create an accurate estimate of the total number of years of dialysis treatment the kidney transplant averted. This level of complexity would also introduce operational risks and burden. This approach would be aligned with the goals of the IOTA Model as it relates to increasing the number and access to kidney transplants but would still require CMS to separately assess performance on proposed performance measures for the IOTA Model, as discussed in section III.C.5.c., d., and e. of this proposed rule.

We are soliciting feedback from the public on our proposal to assess IOTA participant performance in three domains: (1) achievement domain; (2) efficiency domain; and (3) quality domain. We are also seeking feedback on our proposed performance scoring approach that would weigh the achievement domain higher than the efficiency and quality domain, and our proposed use of a 0 to 100 performance scoring approach to determine if and how performance-based payments would apply. Additionally, we invite feedback on the alternatives considered.

c. Achievement Domain

As stated in section III.C.5.b. of this proposed rule, we propose measuring IOTA participant performance across three domains, one of which is the achievement domain. We propose to define ''achievement domain'' as the performance assessment category in which CMS assesses the IOTA participant's performance based on the number of transplants performed on patients 18 years of age or older, relative to a target, subject to a health equity performance adjustment, as described in section III.C.5.c.(3). of this proposed rule, during a PY. We propose to use OPTN data, regardless of payer, and Medicare claims data to calculate the number of kidney transplants performed during a PY by an IOTA participant on patients 18 years of age or older at the time of transplant, as described in section III.C.5.c.(2). of this proposed rule.

We propose to set the participant-specific target for the achievement domain based on each IOTA participant's historic number of transplants. A central goal of the proposed IOTA Model test is to increase the number of kidney transplants furnished by IOTA participants, which we believe would be possible via care delivery transformation and improvement activities, including donor acceptance process improvements to reduce underutilization and discards of donor kidneys. We believe IOTA participants may also increase the number of kidney transplants furnished to patients by improving or implementing greater education and support for living donors.

We considered constructing and using a transplant waitlisting rate measure or using SRTR's transplant rate [188] rather than measuring number of transplants performed relative to a participant-specific target for the achievement domain. Research has suggested that including such a metric could demonstrate the need for both living and deceased donor organs for a particular transplant hospital and be less reliant on organ availability for a particular geographical area.[189] Research also suggests that the inclusion of a pretransplant measure, such as waitlisting rate, may allow for a more complete assessment of transplant hospital performance and provide essential information for patient decision-making.[190] However, for the IOTA Model, we propose to test the effectiveness of the model's incentives to change outcomes, rather than on processes. The relevant outcome for purposes of the IOTA Model is the

[188] For additional information on SRTR's transplant rate measure, please see *https://www.srtr.org/about-the-data/technical-methods-for-the-program-specific-reports#figurea2*.

[189] Paul, S., Melanson, T., Mohan, S., Ross-Driscoll, K., McPherson, L., Lynch, R., Lo, D., Pastan, S.O., & Patzer, R.E. (2021). Kidney transplant program waitlisting rate as a metric to assess transplant access. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 21*(1), 314–321. *https://doi.org/10.1111/ajt.16277*.

[190] Paul, S., Melanson, T., Mohan, S., Ross-Driscoll, K., McPherson, L., Lynch, R., Lo, D., Pastan, S.O., & Patzer, R.E. (2021). Kidney transplant program waitlisting rate as a metric to assess transplant access. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 21*(1), 314–321. *https://doi.org/10.1111/ajt.16277*.

receipt of a kidney transplant, not getting on and remaining on the kidney transplant waitlist. Additionally, the SRTR transplant rate measure calculates the number of those transplanted as a share of the kidney transplant hospital's waitlist, which we believe does not reflect the variety of ways that kidney transplant hospitals construct their waitlist practices. For example, for some kidney transplant hospitals, the number of kidneys transplanted as a share of their ''active'' waitlist transplant candidates may be a more accurate representation of their waitlist practices. Thus, we did not believe this was appropriate to propose for the IOTA Model.

We seek comment on our proposed achievement domain performance metric and alternative methodologies considered for assessing transplant rates.

(1) Calculation of Transplant Target

We propose that for each model PY, CMS would calculate a ''transplant target'' for each IOTA participant, which would determine performance in the achievement domain. For the purposes of the model, we propose to define ''transplant target'' as the target number of transplants set for each IOTA participant to measure performance in the achievement domain as described in section III.C.5.c. of this proposed rule. We propose that CMS would notify each IOTA participant of their transplant target by the first day of each PY, in a form and manner determined by CMS.

For each PY, we propose that CMS would calculate the transplant target for the achievement domain by first determining the highest number of deceased donor kidney transplants and living donor kidney transplants furnished to patients 18 years of age or older in a single year during the baseline years, as defined in section III.C.3.c. of this proposed rule. CMS would then sum the highest number of deceased donor kidney transplants and living donor kidney transplants furnished in a single year during the baseline years calculate the transplant target for an IOTA participant, even if those transplant numbers were achieved during different baseline years. We believe that choosing the highest transplant numbers during the baseline years would illustrate the capabilities and capacities of the IOTA participant, and, when combined, would be an appropriate target for number of transplants performed during the PY. We also understand that living donation and deceased donor donation involve different processes by the IOTA participant, so we are choosing each of those numbers separately to recognize the potential capacity for each IOTA participant for both living and deceased donor transplantation.

We propose that the sum of the highest number of deceased donor and living donor transplants across the baseline years of the IOTA participant would then be projected forward by the national growth rate, as described in section III.C.5.c.(1). of this proposed rule, or zero should the national growth rate be negative, resulting in the transplant target for a given PY. We propose to define ''national growth rate'' as the percentage increase or decrease in the number of kidney transplants performed over a twelve-month period by all kidney transplant hospitals except for pediatric kidney transplant hospitals and kidney transplant hospitals that fall below the low volume threshold described in section III.C.3. of this proposed rule. We propose to define ''pediatric kidney transplant hospitals'' as a kidney transplant hospital that performs 50 percent or more of its transplants in a 12-month period on patients under the age of 18. We are also proposing that the low volume threshold to be 11 kidney transplants performed for the purposes of calculating the national growth rate. We also propose this approach for calculating the national growth rate to account for and reflect the growth in organ procurement by OPOs that has occurred, indicating potential growth in the number of available organs.

We propose that CMS would calculate the national growth rate by determining the percent increase or decrease of all kidney transplants furnished to patients 18 years of age or older from two years prior to the PY to one year prior to the PY. Because the proposed national growth rate includes IOTA participants and non-IOTA participant kidney transplant hospitals, we acknowledge that it could make achieving the transplant target number harder. This is why, if the national growth rate becomes negative for a PY, we propose treating it as zero and CMS would not apply the national growth rate to project forward the sum of the highest number of deceased and living donor kidney transplants furnished in a single year during the baseline years. In other words, an IOTA participant's transplant target would equal the sum of its own highest deceased and living donor transplants furnished across the baseline years if the national growth rate were to be negative for a PY. We also want to be able to share model performance targets with IOTA participants before the start of each PY and are prioritizing ensuring prospectivity over ensuring the most up-to-date trend figures. We also propose that if the model begins on an any date after January 1, 2025, the trend would also be adjusted.

For example, to calculate the national growth rate for PY 1 using the proposed model start date of January 1, 2025, CMS would first subtract the total number of kidney transplants furnished to patients 18 years of age or older in 2022 from the total number of kidney transplants furnished to patients 18 years of age or older in 2023. Next, CMS would then divide that number by the total number of kidney transplants furnished to patients 18 years of age or older in 2022 to determine national growth rate. To create the transplant target for each IOTA participant for PY 1 CMS would do the following:

- If the national growth rate is positive, CMS would trend the national growth rate forward for an IOTA participant by multiplying the national growth rate by the sum of the highest number of deceased donor and living donor transplants furnished to patients 18 years of age or older across the baseline years for the IOTA participant.
- CMS would take the product of step 1 and add it to the sum of the highest living donor and deceased donor kidney transplants furnished to patients 18 years of age or old across the baseline years for an IOTA participant.
- The sum of step 2 would be the transplant target for an IOTA participant. However, if the national growth rate were negative, CMS would not trend the growth rate forward for PY 1 and the transplant target would be the sum of the highest living donor and deceased donor kidney transplants across the baseline years.

We propose that when calculating the national growth rate for each PY, CMS would look to the relevant baseline years for that PY, as depicted in Table 1. This approach would mitigate our concern that a static baseline may reward a one-time investment, rather than continuous improvement. The model PYs, as proposed, would not factor into an IOTA participant's transplant target calculation until PY 3 of the model (January 1, 2027, to December 31, 2027) and the baseline years would not be based exclusively on PYs until PY 5 of the model (January 1, 2029, to December 31, 2029), which may represent an effective phase-in approach to drive improved performance and savings for the Medicare trust fund. We believe that using baseline years to calculate the transplant targets would also account for kidney transplant hospitals that experience changes in strategy or staffing that may affect their

capacity to perform transplants at the level that they did in previous years.

TABLE 1: EXAMPLE – PROPOSED BASELINE YEARS FOR CALCULATION OF TRANSPLANT TARGET (FOR PROPOSED MODEL START DATE)

Performance Year	Calendar Year	Highest Number of Living + Highest Number of Deceased from Baseline Years	Trended by National Growth Rate from
1	Jan 1, 2025 — December 31, 2025	CY 2021: January 1, 2021 – December 31, 2021 CY 2022: January 1, 2022 – December 31, 2022 CY 2023: January 1, 2023 – December 31, 2023	CY 2023/CY 2022
2	Jan 1, 2026 — December 31, 2026	CY 2022: January 1, 2022 – December 31, 2022 CY 2023: January 1, 2023 – December 31, 2023 CY 2024: January 1, 2024 – December 31, 2024	CY 2024/CY 2023
3	Jan 1, 2027 — December 31, 2027	CY 2023: January 1, 2023 – December 31, 2023 CY 2024: January 1, 2024 – December 31, 2024 CY 2025: January 1, 2025 — December 31, 2025	CY 2025/ CY 2024
4	Jan 1, 2028 — December 31, 2028	CY 2024: January 1, 2024 – December 31, 2024 CY 2025: January 1, 2025 – December 31, 2025 CY 2026: January 1, 2026 – December 31, 2026	CY 2026/ CY 2025
5	Jan 1, 2029 — December 31, 2029	CY 2025: January 1, 2025 – December 31, 2025 CY 2026: January 1, 2026 – December 31, 2026 CY 2027: January 1, 2027 – December 31, 2027	CY 2027/ CY 2026
6	Jan 1, 2030 — December 31, 2030	CY 2026: January 1, 2026 – December 31, 2026 CY 2027: January 1, 2027 – December 31, 2027 CY 2028: January 1, 2028 – December 31, 2028	CY 2028/ CY 2027

Should we finalize a model start date other than January 1, 2025, we propose that the baseline years, as defined in section III.B.2.c. of this proposed rule, would shift accordingly, as illustrated in Table 2.

TABLE 2: EXAMPLE - PROPOSED BASELINE YEARS FOR CALCULATION OF TRANSPLANT TARGET, FOR POTENTIAL ALTERNATIVE MODEL START DATE

Performance Year	Alternative Year	Highest Number of Living + Highest Number of Deceased from Baseline Years	Trended by National Growth Rate from
1	July 1, 2025 — June 30, 2026	July 1, 2021 – June 30, 2022 July 1, 2022 – June 30, 2023 July 1, 2023 – June 30, 2024	July 1, 2023 – June 30, 2024 / July 1, 2022 – June 30, 2023
2	July 1, 2026 — June 30, 2027	July 1, 2022 – June 30, 2023 July 1, 2023 – June 30, 2024 July 1, 2024 – June 30, 2025	July 1, 2024 – June 30, 2025 / July 1, 2023 – June 30, 2024
3	July 1, 2027 — June 30, 2028	July 1, 2023 – June 30, 2024 July 1, 2024 – June 30, 2025 July 1, 2025 – June 30, 2026	July 1, 2025 – June 30, 2026 / July 1, 2024 – June 30, 2025
4	July 1, 2028 — June 30, 2029	July 1, 2024 – June 30, 2025 July 1, 2025 – June 30, 2026 July 1, 2026 – June 30, 2027	July 1, 2026 – June 30, 2027 / July 1, 2025 – June 30, 2026
5	July 1, 2029 — June 30, 2030	July 1, 2025 – June 30, 2026 July 1, 2026 – June 30, 2027 July 1, 2027 – June 30, 2028	July 1, 2027 – June 30, 2028 / July 1, 2026 – June 30, 2027
6	July 1, 2030 — June 30, 2031	July 1, 2026 – June 30, 2027 July 1, 2027 – June 30, 2028 July 1, 2028 – June 30, 2029	July 1, 2028 – June 30, 2029 / July 1, 2027 – June 30, 2028

We believe that IOTA participants could improve on this metric in several ways. For example, IOTA participants could increase the number of kidney organ offers they accept, which would also potentially lead to greater efficiency domain scores. IOTA participants could also invest in a living donation program or modify their OR schedules to facilitate fewer discards due to physician scheduling.

We considered basing the transplant target on the total number of all organ transplants performed by the IOTA participant over the baseline years. However, we did not believe this was appropriate because the total would not reflect the specific capabilities of the IOTA participant's kidney transplant program. We also considered adjusting the transplant target by IOTA participant revenue from hospital cost reports. In this scenario, our consideration was to look at historical kidney transplant data as the best predictor, since this reveals the demonstrated capacity for each IOTA

participant to complete kidney transplants.

We also considered setting each IOTA participant's transplant target by determining the IOTA participant's average total kidney transplant volume from the three previous years instead of using the sum of the highest living and deceased donor kidney transplant volumes during the baseline years. We believe this methodology would be simpler and result in a transplant target that is potentially more attainable for IOTA participants, assuming that the average kidney transplant volume is lower than the sum of the highest volumes of deceased and living donor kidney transplants. However, we do not believe that this would reflect the potential highest capacity for transplant that we would otherwise like the target to reflect.

We alternatively considered a static or fixed baseline approach for purposes of determining the transplant target for each IOTA participant, as it would minimize operational burden for CMS due to less frequent updates to the transplant target and ensure that the model does not set a moving target year-over-year. However, we believe that a fixed baseline may reward a one-time investment, rather than continuous improvement, and may not account for kidney transplant hospitals that experience changes in strategy or staffing that may affect their capacity to perform transplants at the level that they did in historical years. The rolling baseline approach we are instead proposing uses historical kidney transplant volumes pre-dating the model start date through the first two model PYs, ensuring a phased-in approach before any improvements made during the model performance period are accounted for in the baseline.

We also considered setting the transplant target for IOTA participants based on two baseline years, rather than the proposed methodology of three. For the proposed model start date of January 1, 2025, this approach would look at the highest living and deceased volumes from 2022 and 2023, trended by the national growth rate from 2024, to set the transplant target for PY 1. We believe this methodology would be more reflective of recent transplantation volume and account for the changes to the kidney allocation system that were implemented in 2021. However, we believe that using two baseline years to set a transplant target would be more susceptible to temporary market disruptions or fluctuations that may impact IOTA participants capability or capacity to furnish kidney transplants, such as: if the transplant hospital experiences a shortage in transplant surgeons or other critical staff; if the transplant hospital is acquired; or, the occurrence of a natural disaster, pandemic, or other public health emergency or other extreme and uncontrollable circumstance that would require the transplant hospital to temporarily suspend operations. Any of these disruptions or fluctuations could result in an inaccurate transplant target that would not accurately reflect an IOTA participant's volume capability.

We considered determining the national growth rate by calculating separately; (1) the growth rate of the deceased donor target number by the growth in organs procured, and (2) the living donor target number by the national growth rate in living donor transplants. However, procurement rates vary nationally depending on variables unique to each geography and local OPO policies.[191] Because we want the model to inspire kidney transplant hospitals to expand living donor programs, not just match national growth rates, we did not believe this alternative methodology was appropriate to propose.

We also considered determining the national growth rate using the following information: (1) the total growth rate in kidney transplants; (2) the change in rate of organs procured by OPOs; (3) the growth rate in kidney transplants in the non-selected portions of the country; and (4) calculating the average growth rate across multiple baseline years. However, we believe that the national growth rate in kidney transplants makes the most sense to use as the basis for the model's growth factor because it best reflects volume trends in the kidney transplant ecosystem overall, as it considers all kidney transplant hospitals, not just IOTA participants.

Finally, we also considered a performance assessment methodology for IOTA participants already achieving higher rates of kidney transplantation by assessing each such IOTA participant's total transplant volume as compared to all IOTA participants, rather than on an IOTA participant specific transplant target. We believe this methodology is both easy to understand and simple to administer because it rewards IOTA participants for the total number of transplants performed. However, we believe this methodology would not be fair to IOTA participants that are smaller in size or achieving lower rates of kidney transplantation.

We solicit comment on our proposal to set unique transplant targets for each IOTA participant, the methodology for setting transplant targets, and any alternatives considered.

(2) Calculation of Points

We propose that the achievement domain would be worth 60 points. We chose this domain for the highest number of points because we believe that driving an increase in the number of transplants should be the main incentive for change in the model. We considered allocating fewer points to this domain, such as 50 points, but we believe that performance in this domain should impact the overall performance score more than the other domains given its centrality to the model.

We propose that an IOTA participant's performance would be assessed relative to their transplant target, with those performing at less than 75 percent of the transplant target receiving no points and those performing at 150 percent of the transplant target or above receiving the maximum number of points (60 points). That is, at the highest end of the scale, IOTA participants performing at or above 150 percent of the transplant target would earn the maximum 60 points, while at the lowest end of the scale, IOTA participants performing at less than 75 percent of the transplant target would earn no points for the achievement domain; performance that falls in between 75 percent and 150 percent of the transplant target may earn the IOTA participant 45, 30, or 15 points in the achievement domain. Table 3 illustrates our proposal for how an IOTA participant's performance would be assessed against its transplant target. We chose 150 percent as the maximum performance level based on the theoretical capability of growth in one year and analysis in trends of transplant over time. We recognize that an IOTA participant might exceed 150 percent of its transplant target, but this is not expected given the investment needed for substantiable transplant infrastructure to consistently support that number of transplants over time.

[191] Potluri, V.S., & Bloom, R.D. (2021). *Effect of Policy on Geographic Inequities in Kidney Transplantation. https://doi.org/10.1053/j.ajkd.2021.11.005;* Hanaway, M.J., MacLennan, P.A., & Locke, J.E. (2020). Exacerbating Racial Disparities in Kidney Transplant. *JAMA Surgery, 155*(8), 679. *https://doi.org/10.1001/jamasurg.2020.1455.*

TABLE 3: PROPOSED ASSESSMENT OF ACHIEVEMENT DOMAIN

Performance Relative to Transplant Target	Lower Bound Condition	Upper Bound Condition	Points Earned
150% of transplant target	Equals 150%	Greater than 150%	60
125% of transplant target	Equals 125%	Less than 150%	45
100% of transplant target	Equals 100%	Less than 125%	30
75% of transplant target	Equals 75%	Less than 100%	15
75% of transplant target	N/A	Less than 75%	0

We believe that a methodology based on performance improvement relative to historical performance is important and would allow us to test whether the model's performance based payments drive increased behavior from IOTA participant, as opposed to just rewarding IOTA participants based on the status quo. IOTA participants that are achieving a high rate of kidney transplantation, and already have robust transplant programs at the start, can more easily scale up to achieve the additional growth required for excellent performance under the model. Also, given our statutory requirements to achieve savings, the CMS Office of the Actuary (OACT) estimates, as described in section VI of this proposed rule, suggest that savings would be driven by the effects of increased transplants. We believe that the model's performance based payments need to be tied to a policy that aims to create and drive Medicare savings.

We considered offering differential credit for transplants by type. With this methodology, IOTA participants would receive bonus points and score higher for transplants that fit into categories that lead to more savings, such as living donor kidney transplants (LDK), high KDPI donors, or pre-emptive transplants, compared to other transplants. However, we believe that counting all transplants the same, except for transplants furnished to underserved populations, would maximize flexibility for IOTA participants in meeting their targets and minimize the potential harm and unintended consequences the alternative system would create.

As an alternative, we considered including gradient points instead of points based on bands (that is, between X and Y). Scoring closer to a performance minimum would result in increased points rather than remaining static throughout the band. We considered the following formula: Percent Performance Relative to Transplant Target * (100/2.5), not to exceed 60 points. However, we decided that a narrower range of results would better differentiate performance among IOTA participants and allow for easier comparison across IOTA participants.

We also considered smaller point brackets of improvement, requiring IOTA participants to achieve a flat number increase of kidney transplants, such as to a 140 percent, 125 percent, or 120 percent, to achieve the highest performance in this category, and asymmetric point brackets that would make the magnitude of performance required to achieve the highest performance rate a flat number increase in addition to a percentage increase. However, we wanted the percentage of the transplant target necessary to achieve the highest number of points to be large enough to incentivize behavior while still being achievable.

We also considered improvement-only scoring, based on year-over-year IOTA participant transplant growth, without inclusion of national rates. In this methodology, positive improvement rates less than 5 percent would be scored 15 points, rates over 5 percent would be scored 30 points, rates over 20 percent would be scored 45 points, and rates over 50 percent would be scored 60 points. We also considered using combinations of potential transplant target or scoring methods, with the final score being whichever score was highest to ensure low-volume IOTA participants are not penalized and to mitigate unrealistic transplant targets. We considered an improvement-only scoring methodology to reflect the historical performance of each IOTA participant. However, because we want a methodology that sets more of a national standard for expected growth rate to assess volume trends in the transplant space overall, we chose not to propose improvement-only scoring. As organ supply continues to increase year-over-year, we wish to set the expectation for IOTA participants to grow their transplant volumes at least at the cadence of the national growth rate.

We solicit comment on our proposed achievement domain scoring methodology and alternative methodologies considered.

(3) Health Equity Performance Adjustment

Socioeconomic factors impact patient access to kidney transplants. Patients with limited resources or access to care may require more assistance from kidney transplant hospitals to overcome barriers to transplantation. To incentivize IOTA participants to decrease disparities in the overall transplant rate among patients of various income levels, we propose to include a health equity performance adjustment in the methodology for calculating the overall number of transplants furnished to patients attributed to an IOTA participant during the PY. We propose to define the ''health equity performance adjustment'' as the multiplier applied to each kidney transplant furnished to a low-income population IOTA transplant patient when calculating the transplant target as described in § 512.424). For purposes of the model, we propose to define the ''low-income population'' to mean an IOTA transplant patient in one or more of the following groups:

- The uninsured.
- Medicaid beneficiaries.
- Medicare-Medicaid dually eligible beneficiaries.
- Recipients of the Medicare LIS.
- Recipients of reimbursements from the Living Organ Donation Reimbursement Program administered by the National Living Donor Assistance Center (NLDAC).

We propose to apply a health equity performance adjustment, a 1.2 multiplier, to each kidney transplant furnished by an IOTA participant to a patient, 18 years of age or older at the time of transplant, that meets the low-income population definition. That is, each kidney transplant that is furnished to a patient who meets the low-income population definition would be multiplied by 1.2, thus counting that transplant as 1.2 instead of 1. The resulting count of the overall number of

kidney transplants performed during the PY, after the health equity performance adjustment is applied, would then be compared to the transplant target. In effect, the health equity performance adjustment would be a reward-only adjustment to the performance score in the achievement domain. We also considered basing the multiplier on the difference between rates of transplantation for Medicare beneficiaries with ESRD who are dual eligible and those who are not. In 2019, 47 percent of Medicare beneficiaries with ESRD were dually eligible for Medicare. However, only 41 percent of Medicare transplants recipients were dually eligible, which would yield a multiplier of 1.1.[192]

We chose 1.2 as the health equity performance adjustment multiplier because, according to USRDS data, 78.6 percent of patients living with ESRD have some form of Medicare and or Medicaid coverage; however only 65.1 percent of patients who received transplants in 2020 were on Medicare, Medicaid, or both.[193] [194] The 1.2 multiplier represents the ratio of those living with ESRD and those who received transplants. We theorize that providing this incentive for IOTA participants to increase their transplant rate among low-income populations would ultimately reduce disparities in access to kidney transplants, as it would encourage IOTA participants to address access barriers low-income patients often face, such as transportation, remaining active on the kidney transplant waiting list, and making their way through the living donation process.

We believe the health equity performance adjustment would be a strong incentive to promote health equity, as the multiplier earned would help IOTA participants meet or exceed their kidney transplant target, thereby potentially resulting in upside risk payments given the heavy weighted scoring applied to the achievement domain. We also believe it would ensure IOTA participants that serve disproportionately high numbers of low-income populations are not penalized in the achievement performance scoring.

We considered not applying a health equity performance adjustment to the achievement performance scoring, which would ensure all kidney transplants, regardless of the low-income status of individual patients, are counted as one transplant. The concern with the health equity performance adjustment may be that it may incentivize shifting of kidney transplants from one type of patient to another. However, we believe the incentive is to promote improvement activities that would increase access to all patients while recognizing that low-income patients may face more barriers to care outside of the IOTA participants' control. It also recognizes that disparities already exist in access to kidney transplants for low-income patients, so, by addressing inequities, IOTA participants would focus efforts on tackling inequities for patients outside the Medicare population.

For purposes of the health equity performance adjustment, we also considered using the area deprivation index (ADI) to define the low-income population. ADI ranks neighborhoods based on socioeconomic disadvantage in the areas of income, education, employment, and housing quality. Areas with greater disadvantage are ranked higher, and they correlate with worse health outcomes in measures such as life expectancy.[195] The areas used in the ADI are defined by Census Block Group, which presents a number of challenges.[196] However, because address information for Medicare beneficiaries may be incomplete, and not available at all for patients who have private insurance or the uninsured, we opted to not use ADI to define the low-income population. We believe that this would leave an incomplete picture of the transplant population for a given IOTA participant. Furthermore, the socioeconomic status of individuals within a given ADI can vary greatly. Those that are underserved in a Census Block Group with a low ADI may be overlooked.

We also considered including ''rural resident'' as one of the groups that define a low-income population in the IOTA Model, as rural transplant patients face numerous barriers to care, including transportation, food, housing, and income insecurity, and no or limited access to kidney transplant hospitals within or close to their rural communities. We considered defining rural beneficiaries consistent with the criteria used for identifying a rural area when determining CAH eligibility at 42 CFR part 485.610(b)(1)(i), that is beneficiaries living outside an MSA. However, we were unsure if it was appropriate to include this group to define a low-income population to determine if a health equity adjustment would apply to the achievement performance score, particularly as the proposed low-income definition may already capture the majority of rural kidney transplant patients.

We seek comment on our proposed health equity performance adjustment, including on the adjustment multiplier and calculation method, the definition of low-income population and alternatives considered, including consideration of ADI as an alternative definition, or including rural resident in the low-income population definition.

d. Efficiency Domain

We propose to define the ''efficiency domain'' as the performance assessment category in which CMS assesses the IOTA participant's performance a metric intended to improve the transplant process, as described in section III.C.5.d.(1). of this proposed rule, during a PY. The efficiency domain is focused on improving the overall efficiency of the transplant ecosystem.

We propose including OPTN's organ offer acceptance rate measure in the efficiency domain. The organ offer acceptance rate ratio measure is a ratio of observed organ offer acceptances versus expected organ offer acceptances, as described in section III.C.5.d.(1). of this proposed rule.

(1) Organ Offer Acceptance Rate Ratio

With over 90,000 unique patients on the waitlist for a kidney transplant, the need to effectively use every available donor organ is critical. However, despite the new allocation system introduced in 2021, and more organs being offered over a wider geographic area, the kidney discard rate has risen to over 24.6 percent and continues to trend upwards.[197] There is a significant shortage of organs available for transplantation, and many patients die waiting for a kidney transplant. Moreover, there are large disparities in organ offer acceptance ratio performance. A 2020 national registry

[192] Gillen, E.M., Ganesan, N., Kyei-Baffour, B., & Gooding, M. (2021, August 30). *Avalere analysis of disparities in Kidney Care Service Utilization.* Avalere Health. *https://avalere.com/insights/avalere-analysis-of-disparities-in-kidney-care-service-utilization.*

[193] United States Renal Data System. (2020). *2020 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.

[194] Lentine, K. L., Smith, J. M., Hart, A., Miller, J., Skeans, M. A., Larkin, L., Robinson, A., Gauntt, K., Israni, A. K., Hirose, R., & Snyder, J. J. (2022). OPTN/SRTR 2020 Annual Data Report: Kidney. *American Journal of Transplantation, 22*(S2), 21–136. *https://doi.org/10.1111/ajt.16982 https://doi.org/10.1111/ajt.16982.*

[195] *Neighborhood Atlas—Home.* (2018). Wisc.edu. *https://www.neighborhoodatlas.medicine.wisc.edu/.*

[196] *https://www2.census.gov/geo/pdfs/reference/GARM/Ch11GARM.pdf.*

[197] MN, 1Scientific R. of T. R., Hennepin Healthcare Research Institute, Minneapolis. (n.d.). *Kidney. Srtr.transplant.hrsa.gov.* Retrieved June 19, 2023, from *https://srtr.transplant.hrsa.gov/annual_reports/2021/Kidney.aspx.*

study found that the probability of receiving a deceased donor kidney transplant within three years of placement on the waiting list varied 16-fold between different kidney transplant hospitals across the U.S.[198] The study also found that large variations were still present between kidney transplant hospitals that utilized the same OPO and that the probability of transplant was significantly associated with transplant hospitals' offer acceptance rates.[199] By incentivizing kidney organ offer acceptance, we aim to optimize the use of available organs, thereby reducing underutilization and discards of quality donor organs.

For purposes of assessing the performance of IOTA participants in the achievement domain, we propose to include the organ offer acceptance rate ratio as one of the two metrics of performance. We believe that including this measure in the efficiency domain would encourage IOTA participants to increase the utilization of available organs. We also believe that this measure would encourage IOTA participants to improve efficiency in the organ offer process, improve acceptance practices for offers received, and allow for maximal utilization of available organs. We believe that the organ offer acceptance rate ratio is an important system-wide metric, as improved performance by an IOTA participant would also improve opportunities for other kidney transplant hospitals that would not have to wait as long for an available donor kidney. We recognize that all kidney transplant hospitals are already assessed on the organ offer acceptance rate ratio metric under the OPTN, however, we believe that the IOTA Model sets a higher bar for performance, as discussed in section III.C.5.d.(1).(a). of this proposed rule, rather than clearing the threshold that the OPTN sets at 0.30.[200]

In the United States, kidney transplant waitlist candidates face considerable disparities in access to kidney transplant, such as in who is referred and placed on the waiting list, who remains ''active'' on the waiting list, and how waitlisted patients are managed by kidney transplant hospitals.[201] Additionally, kidney transplant hospital performance is commonly measured by post-transplant outcomes. We recognize that including pre-transplant measures could allow for a more thorough evaluation of transplant hospital performance and provide insight for patient decision-making.

We considered several waitlist management metrics for assessing performance in the efficiency domain, such as the number of patients registered to a waitlist, the number or percentage of attributed patients registered on a waitlist with an active waitlist status, or the number or percentage of attributed patients on a waitlist with active waitlist status to inactive waitlist status. Metrics focused on the waitlist could help assess how effectively kidney transplant hospitals are managing their kidney transplant waitlist patients. Organ offers to waitlist kidney transplant patients are made directly to the kidney transplant hospital where they are waitlisted. Once a kidney transplant hospital receives an organ offer for one of their kidney transplant waitlist patients, it is ultimately its decision to accept or decline an organ offer on the patient's behalf. Kidney transplant hospitals are not required to inform kidney transplant waitlist patients for whom an offer was received when an organ offer was received or why an organ offer was declined. While we understand the importance of a transplant surgeon's clinical decision-making and respect the clinical judgement of transplant surgeons, declining an offer without involving the affected patient in the decision-making can be detrimental to the patient, as additional time on the waitlist can negatively impact the patient's quality of life.[202]

We also considered including a waitlist mortality metric for assessing efficiency domain performance, so as to incentivize improvements in mortality outcomes of attributed patients on a waitlist. On average, as many as 20 patients on the waitlist for a kidney transplant die each day waiting for a kidney transplant in the United States.[203] While a waitlist mortality metric may help assess patient outcomes and experience while waiting for an organ offer,[204] and provide insight into differences in waitlist management practices across kidney transplant hospitals, we recognize that waitlist mortality rate is also influenced by the insufficient supply of available donor organs available for transplantation. We also recognize that IOTA participants may not have a direct effect on, or ability to improve, mortality metrics, as nephrologists are also closer to the direct care of waitlist patients and would have a greater ability to affect their care and mortality rate. Furthermore, we believe that we are already testing the ability of nephrologists to manage care for Medicare beneficiaries with ESRD or CKD via the KCC Model.

We also considered several other metrics for assessing efficiency domain performance related to time to transplant, such as—

- Time from initial evaluation to transplant;

[198] King, K. L., Husain, S. A., Schold, J. D., Patzer, R. E., Reese, P. P., Jin, Z., Ratner, L. E., Cohen, D. J., Pastan, S. O., & Mohan, S. (2020). Major Variation across Local Transplant Centers in Probability of Kidney Transplant for Wait-Listed Patients. *Journal of the American Society of Nephrology, 31*(12), 2900–2911. *https://doi.org/10.1681/ASN.2020030335.*

[199] King, K. L., Husain, S. A., Schold, J. D., Patzer, R. E., Reese, P. P., Jin, Z., Ratner, L. E., Cohen, D. J., Pastan, S. O., & Mohan, S. (2020). Major Variation across Local Transplant Centers in Probability of Kidney Transplant for Wait-Listed Patients. *Journal of the American Society of Nephrology, 31*(12), 2900–2911. *https://doi.org/10.1681/ASN.2020030335.*

[200] *Enhance Transplant Program Performance Monitoring System OPTN Membership and Professional Standards Committee.* (n.d.). *https://optn.transplant.hrsa.gov/media/4777/transplant_program_performance_monitoring_public_comment_aug2021.pdf.*

[201] Schold, J.D., Gregg, J.A., Harman, J.S., Hall, A.G., Patton, P.R., & Meier-Kriesche, H.U. (2011). Barriers to Evaluation and Wait Listing for Kidney Transplantation. *Clinical Journal of the American Society of Nephrology, 6*(7), 1760–1767. *https://doi.org/10.2215/cjn.08620910*; Hod, T., & Goldfarb-Rumyantzev, A.S. (2014). *The role of disparities and socioeconomic factors in access to kidney transplantation and its outcome. Renal Failure, 36*(8), 1193–1199. *https://doi.org/10.3109/0886022x.2014.934179;* Stolzmann, K.L., Bautista, L.E., Gangnon, R.E., McElroy, J.A., Becker, B.N., & Remington, P.L. (2007). Trends in kidney transplantation rates and disparities. *Journal of the National Medical Association, 99*(8), 923–932. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2574300/*; Paul, S., Melanson, T., Mohan, S., Ross-Driscoll, K., McPherson, L., Lynch, R., Lo, D., Pastan, S.O., & Patzer, R.E. (2021). Kidney transplant program waitlisting rate as a metric to assess transplant access. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 21*(1), 314–321. *https://doi.org/10.1111/ajt.16277;* Cheng, X.S., Busque, S., Lee, J., Discipulo, K., Hartley, C., Tulu, Z., Scandling, J. ., & Tan, J.C. (2018). A new approach to kidney wait-list management in the kidney allocation system era: Pilot implementation and evaluation. *Clinical Transplantation, 32*(11), e13406. *https://doi.org/10.1111/ctr.13406.*

[202] Husain, S.A., King, K.L., Pastan, S., Patzer, R.E., Cohen, D.J., Radhakrishnan, J., & Mohan, S. (2019). Association Between Declined Offers of Deceased Donor Kidney Allograft and Outcomes in Kidney Transplant Candidates. *JAMA Network Open, 2*(8), e1910312. *https://doi.org/10.1001/jamanetworkopen.2019.10312.*

[203] Delmonico, F.L., & McBride, M.A. (2008). Analysis of the Wait List and Deaths Among Candidates Waiting for a Kidney Transplant. *Transplantation, 86*(12), 1678–1683. *https://doi.org/10.1097/tp.0b013e31818fe694.*

[204] Shepherd, S., & Formica, R.N. (2021). *Improving Transplant Program Performance Monitoring. 8*(4), 293–300. *https://doi.org/10.1007/s40472-021-00344-z;* Wey, A., Gustafson, S.K., Salkowski, N., Kasiske, B.L., Skeans, M., Schaffhausen, C.R., Israni, A.K., & Snyder, J.J. (2019). *Association of pretransplant and posttransplant program ratings with candidate mortality after listing. 19*(2), 399–406. *https://doi.org/10.1111/ajt.15032.*

- Time from initial referral to transplant;
- Time from initial placement on a waitlist to transplant; and
- Time from when a patient was initially referred to time of initial evaluation to time of initial placement on a waitlist to time to transplant.

Before a patient can be considered for, and placed on, the waiting list for a kidney transplant, they must first be referred by either a nephrologist or dialysis facility, at which point they undergo a comprehensive evaluation process by a transplant hospital.[205] Studies have shown long-standing barriers and disparities to access to transplantation by patient demographics, such as racial/ethnic, sex, socioeconomic, and insurance factors.[206] Disparities are driven by various factors, but we recognize that delays or lack of referrals for evaluation, evaluation criteria that may unintentionally deem a patient not eligible to be placed on a waitlist, and organ acceptance rate variations across kidney transplant hospitals, may exacerbate disparities. Thus, measuring time to transplant was considered an appropriate potential performance metric that could incentivize IOTA participants to improve. However, we chose not to propose this type of measure due to concerns about how to properly measure start and end points and unintended consequences that may harm patients, as it may create opportunities for kidney transplant hospitals to manipulate average times by only adding patients to the waitlist when they are certain of imminent transplant, which could exacerbate waitlist inequities.

We also considered including a transplantation referral to evaluation conversion rate measure. For patients with ESRD, access to transplantation is influenced by both referral patterns of pre-transplantation providers and transplant hospital processes of care and evaluation criteria.[207] Additionally, some studies found considerable variation in referral rates to transplantation by dialysis facilities, proposing significant regional and facility-level variation in care.[208] However, because dialysis facilities are often the primary referrer and are not IOTA participants, we did not propose this measure. We also have concerns about how this data would be collected.

Finally, we also considered a living donor rate as one of the metrics used to assess performance in the efficiency domain to measure percentage of potential living donors who are evaluated to donate a kidney and that actually donated a kidney. This metric could help assess success towards addressing living donor concerns and improvements in education on the living donor process. However, we did not propose this metric because we have concerns about our ability to access data needed for measurement.

Ultimately, we chose not to propose to include waitlist management metrics when assessing IOTA participant performance in the efficiency domain because we believe that costs are already accounted for in the Medicare cost report. Transplant waitlist measures also do not capture living donation, which is an additional path to a successful kidney transplant that CMS already incentivizes living donations in the ETC Model. Moreover, studies have shown that organ acquisition costs have been rising and were not solely attributable to the cost of procurement, suggesting that an increased focus on the waiting list could further increase Medicare expenditures.[209] Also, for some of the measures considered (that is, waitlist mortality, transplantation referral to evaluation rate), nephrologists and dialysis facilities play large roles in maintaining the patient's health, and we do not believe it is appropriate to include a measure that would depend largely upon the behavior and actions of physicians and facilities other than the IOTA participant. We also believe this type of measure could distract from increasing rates of transplant and provide false expectations for time to transplant for kidney transplant waitlist patients. We are also concerned that a waitlist measure could have unintended consequences and potentially lead to those most in need of transplant not being listed to receive a transplant.

We solicit comment on our proposed organ offer acceptance rate ratio metric for purposes of assessing performance in the efficiency domain, and the alternatives considered.

(a) Calculation of Metric

We propose calculating organ offer acceptance rates for an IOTA participant using OPTN's offer acceptance rate ratio performance metric (see Equation 1). Per OPTN's new offer acceptance rate ratio, a rate ratio for a kidney transplant hospital that is greater than 1 indicates that the kidney transplant hospital usually accepts more offers than expected. A rate ratio that is less than 1 conveys a kidney transplant hospital's tendency to accept fewer offers than expected compared to national offer acceptance practices.[210] The OPTN MPSC has reported that this metric assesses kidney transplant hospitals' rate of observed organ offer acceptances to expected acceptances and is intended to answer the following question: Given the types of offers received to the specific candidates, does this program accept offers at a rate higher/lower than national experience for similar offers to similar candidates.[211]

[205] Paul, S., Plantinga, L.C., Pastan, S.O., Gander, J.C., Mohan, S., & Patzer, R.E. (2018). Standardized Transplantation Referral Ratio to Assess Performance of Transplant Referral among Dialysis Facilities. *Clinical Journal of the American Society of Nephrology, 13*(2), 282–289. *https://doi.org/10.2215/cjn.04690417;* Redeker, S., Massey, E.K., van Merweland, R.G., Weimar, W., Ismail, S.Y., & Busschbach, J.J.V. (2022). Induced demand in kidney replacement therapy. *Health Policy, 126*(10), 1062–1068. *https://doi.org/10.1016/j.healthpol.2022.07.011;* Knight, R.J., Teeter, L.D., Graviss, E.A., Patel, S.J., DeVos, J.M., Moore, L.W., & Gaber, A.O. (2015). Barriers to Preemptive Renal Transplantation. *Transplantation, 99*(3), 576–579. *https://doi.org/10.1097/tp.0000000000000357;* Schold, J.D., Patzer, R.E., Pruett, T.L., & Mohan, S. (2019). Quality Metrics in Kidney Transplantation: Current Landscape, Trials and Tribulations, Lessons Learned, and a Call for Reform. *American Journal of Kidney Diseases, 74*(3), 382–389. *https://doi.org/10.1053/j.ajkd.2019.02.020.*

[206] Shepherd, S., & Formica, R.N. (2021). *Improving Transplant Program Performance Monitoring. 8*(4), 293–300. *https://doi.org/10.1007/s40472-021-00344-z;* Ernst, Z., Wilson, A., Peña, A., Love, M., Moore, T., & Vassar, M. (2023). Factors associated with health inequities in access to kidney transplantation in the USA: A scoping review. *Transplantation Reviews,* 100751. *https://doi.org/10.1016/j.trre.2023.100751.*

[207] Schold, J.D., Patzer, R.E., Pruett, T.L., & Mohan, S. (2019). Quality Metrics in Kidney Transplantation: Current Landscape, Trials and Tribulations, Lessons Learned, and a Call for Reform. *American Journal of Kidney Diseases, 74*(3), 382–389. *https://doi.org/10.1053/j.ajkd.2019.02.020.*

[208] Ibid; Alexander, G. Caleb., & Sehgal, A.R. (2002). Variation in access to kidney transplantation across dialysis facilities: Using process of care measures for quality improvement. *American Journal of Kidney Diseases, 40*(4), 824–831. *https://doi.org/10.1053/ajkd.2002.35695;* Patzer, R.E., Plantinga, L.C., Paul, S., Gander, J., Krisher, J., Sauls, L., Gibney, E.M., Mulloy, L., & Pastan, S.O. (2015). Variation in Dialysis Facility Referral for Kidney Transplantation Among Patients With End-Stage Renal Disease in Georgia. *JAMA, 314*(6), 582. *https://doi.org/10.1001/jama.2015.8897.*

[209] Cheng, X.S., Han, J., Braggs-Gresham, J.L., Held, P.J., Busque, S., Roberts, J.P., Tan, J.C., Scandling, J.D., Chertow, G.M., & Dor, A. (2022). Trends in Cost Attributable to Kidney Transplantation Evaluation and Waitlist Management in the United States, 2012–2017. *JAMA Network Open, 5*(3), e221847. *https://doi.org/10.1001/jamanetworkopen.2022.1847.*

[210] OPTN. (2022). *OPTN Enhanced Transplant Program Performance Metrics. https://optn.transplant.hrsa.gov/media/r5lmmgcl/mpsc_performancemetrics_3242022b.pdf.*

[211] *Mpsc-enhance-transplant-program-performance-monitoring-system_srtr-metrics.pdf.* (n.d.). Retrieved December 28, 2022, from *https://optn.transplant.hrsa.gov/media/qfuj3osi/mpsc-enhance-transplant-program-performance-monitoring-system_srtr-metrics.pdf.*

Expected acceptances are based solely on kidneys that are accepted and transplanted by a kidney transplant hospital, so unsuitable kidneys are excluded from this measure, and are calculated using logistic regression models to determine the probability that a given organ offer will be accepted. The measure, as specified by SRTR methodology, is inherently risk adjusted as it only counts organs that are ultimately accepted by a kidney transplant hospital.[212] We propose to use SRTR data to calculate the OPTN organ offer acceptance rate ratio, as described in section III.C.5.d.(1).(b). of this proposed rule.

Per the SRTR measure, we propose dividing the number of kidney transplant organs accepted by each IOTA participant (numerator) by the risk-adjusted number of expected organ offer acceptances (denominator).[213] This measure utilizes a logistic regression and risk adjusts for the following: donor quality and recipient characteristics; donor-candidate interactions, such as size and age differences; number of previous offers; and, distance of potential recipient from the donor.[214] We propose to use SRTR's adult kidney model strata risk adjustment methodology and most recently available set of coefficients to calculate the number of expected organ offer acceptances.

For example, suppose we have a model for predicting the probability a kidney offer will be accepted, and this model adjusts for the number of years the candidate has been on dialysis, whether the kidney was biopsied, and the distance between the donor hospital and the candidate's transplant center. Consider the offer of a biopsied kidney 150 nautical miles (NM) away to a candidate who has been on dialysis for 2 years. To calculate the probability of acceptance, we would first multiply these values by their respective model coefficients and then sum up those products with the model's intercept, as illustrated in Table 4.[215]

TABLE 4: EXAMPLE OF SUMMING UP COEFFICIENTS

Risk Adjustment Factor	Value	Coefficient	Product
Kidney Biopsied	Yes (use 1 for yes)	-1.750	-1.750
Years on Dialysis	2	0.250	0.500
Distance (NM)	150	-0.0035	-0.525
Intercept	(use 1 for intercept)	-0.255	-0.225
Total			-2

We would then plug that total into the following equation (see Equation 2) to get that the probability of acceptance is approximately 0.119 (that is, 11.9% chance of acceptance).

Equation 2: Probability of Organ Offer Acceptance

$$Probability\ of\ Organ\ Offer\ Acceptance\ = \frac{e^{-2}}{1+e^{-2}}$$

To determine the number of offers a transplant program was expected to accept, we would add up the probability of acceptance for every offer that transplant program received The final organ offer acceptance rate ratio (OAR) is then constructed from the observed (O) number of acceptances and the expected (e) number of acceptances using equation 1 to paragraph (b)(1) of § 512.426. In this example we showed a simple logistic regression model that only included three risk-adjusters. The actual models used by the SRTR adjust for many more variables, but the process demonstrated here is the same.

A kidney may be transplanted into a candidate who did not appear on the match run, usually to avoid discard if the intended recipient is unable to undergo transplant. If the eventual recipient was not a multi-organ transplant candidate and was blood type compatible per kidney allocation policy, then these transplants would be included in the organ offer acceptance rate. For purposes of the IOTA Model, we propose to define ''match run'' as a computerized ranking of transplant candidates based upon donor and candidate medical compatibility and criteria defined in OPTN policies.

Per OPTN's new organ offer acceptance rate ratio, Table 5 summarizes the types of organ offers that we propose be included and excluded in the calculation of this metric. For the purposes of organ offers excluded from the organ offer acceptance rate ratio, we propose to define ''missing responses'' as organ offers that the kidney transplant hospital received from the OPO but did not submit a response (accepting or rejecting) in the allotted time frame from the time the offer was made per OPTN policy 5.6.B.[216] For purposes of organ offers excluded from the organ offer acceptance rate ratio measure, we

[212] Scientific Registry of Transplant Recipients. (n.d.). *Risk Adjustment Model: Offer Acceptance.* Offer acceptance. *https://www.srtr.org/tools/offer-acceptance/.*

[213] Ibid.

[214] SRTR. (2023). Srtr.org. *https://tools.srtr.org/OAModelApp_2205/;* Ibid.

[215] CMS notes that some risk adjustment factors in the SRTR models may only apply in certain ranges of a continuous variable. For example, a term that applies if the patient's age at the time of listing is >35 may be named ''can_age_at_listing_right_spline_knot_35''. In these cases, obtain the product using this formula if the patient's age at listing was >35: product = (Age − 35)*(model coefficient). Others may apply if the value is less than (<) a specified value. For example, for a term like ''can_age_at_listing_left_spline_knot_18'', obtain the product for a patient younger than 18 as: product = (18 − Age)*(model coefficient).

[216] OPTN. (2023). *OPTN Policies. https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.*

propose to define ''bypassed response'' as an organ offer not received due to expedited placement [217] or a decision by a kidney transplant hospital to have all of its waitlisted candidates skipped during the organ allocation process based on a set of pre-defined filters matching the characteristics of the potential organ to be transplanted.[218]

TABLE 5: ORGAN OFFERS INCLUDED AND EXCLUDED FROM MEASURE[219]

Offers Included in Measure	Offers Excluded from Measure
• Organ offers that are ultimately accepted and transplanted. • Offers to candidates on a single organ waitlist (except for Kidney/Pancreas candidates that are also listed for kidney alone).	• Multiple match runs from same donor combined and duplicate offers. • Match run had no acceptances. • Offer occurred after last acceptance in a match run. • Missing or bypassed response. • Offers to multi-organ candidates (except for Kidney/Pancreas candidates that are also listed for kidney alone).

We believe that IOTA participants could improve on the organ offer acceptance rate ratio metric in at least two ways. First, IOTA participants could increase the number of organ offers they accept, which would also potentially lead to greater performance scores in the achievement domain. Second, IOTA participants could also decrease the number of expected acceptances by adding better filters so that they are only receiving offers that they are likely to accept. Stricter filters may help ensure that an IOTA participant is not delaying the allocation of organs that they are uninterested in that could otherwise be accepted by another kidney transplant hospital. Since there are multiple ways to improve the offer acceptance ratio, the model is not requiring increased utilization of higher KDPI kidneys that some centers may not want to use due to their clinical protocols. Additionally, the IOTA Model is not prescribing or requiring specific care delivery transformation or improvement activities of IOTA participants, so as to allow for flexibility and innovation.

We considered calculating the organ offer acceptance rate by dividing the number of organs each IOTA participant accepts by the number offered to that transplant hospital's patients that are ultimately accepted elsewhere; however, the lack of risk adjustment in this metric may be unfair to some IOTA participants.

We considered calculating the organ offer acceptance rate by dividing the number of organs each IOTA participant accepts by the number offered to that transplant hospital's patients that are ultimately accepted elsewhere; however, the lack of risk adjustment in this metric may be unfair to some IOTA participants.

We also considered updating the calculation for organ offer acceptance rate ratio to account for the benefits of living donation by increasing the number of organs in the system because the proposed organ offer acceptance rate ratio only shows improvement in deceased donor utilization. This modification would add a single 1 in the numerator and a single 1 in the denominator for each living donation a transplant hospital completes. However, we did not propose updating the organ offer acceptance rate ratio because we decided to focus on deceased donor acceptance to remain aligned with the SRTR calculation. We also did not believe this was appropriate to propose because we believe that IOTA participants with an established or high performing living donation program would be able to gain points more easily in the achievement domain, which has a larger percent of overall points, which we believe may be unfair to IOTA participants that do not.

We seek comment on our proposal to use and calculate the OPTN organ offer acceptance rate ratio in accordance with OPTN's measure specifications and SRTR's methodology as the metrics that would determine IOTA participants' performance on the efficiency domain. We also seek comments on the alternatives we considered. Additionally, we seek comment on our proposed definitions.

(b) Calculation of Points

As described in section III.C.5.b. of this proposed rule, we propose that performance on the efficiency domain would be worth up to 20 points of 100 maximum points. As indicated in section III.C.5.c(2) of this proposed rule, the efficiency domain is weighted lower than the achievement domain but equal to the quality domain to ensure performance measurement is primarily

[217] Expedited placement has the potential to minimize delays in organ allocation by directing organs that may not be ideal to transplant centers that have demonstrated a willingness to utilize such organs. Currently, expedited placement, also known as ''accelerated placement'' or ''out-of-sequence'' allocation, permits OPOs to deviate from the standard match run, which determines the priority of patients on the waiting list for organ offers, under exceptional circumstances. This discretionary tool of expedited placement is employed by OPOs when there are suboptimal donor characteristics associated with donor disease or recovery-related issues, in order to prevent the organ from going unused. For numerous years, expedited organ placement has played a crucial role in organ allocation, enabling OPOs to promptly allocate organs that they believe are at risk of not being utilized for transplantation.

[218] King, K.L., S Ali Husain, Cohen, D.J., Schold, J.D., & Mohan, S. (2022). The role of bypass filters in deceased donor kidney allocation in the United States. *American Journal of Transplantation, 22*(6), 1593–1602. *https://doi.org/10.1111/ajt.16967; Transplant Quality Corner | The New MPSC Metric.* (n.d.). The Organ Donation and Transplantation Alliance. Retrieved February 23, 2024, from *https://www.organdonationalliance.org/insights/quality-corner/new-mpsc-metric/.*

[219] OPTN. (2022). *OPTN Enhanced Transplant Program Performance Metrics. https://optn.transplant.hrsa.gov/media/r5lmmgcl/mpsc_performancemetrics_3242022b.pdf; For Transplant Center Professionals.* (n.d.). *Www.srtr.org.* Retrieved February 22, 2023, from *https://www.srtr.org/faqs/for-transplant-center-professionals/#oaconsideration.*

focused on increasing number of kidney transplants, while still incentivizing efficiency and quality. Within the efficiency domain, we propose that the OPTN organ offer acceptance rate ratio would account for the entirety of the 20 allocated points in that domain.

We propose applying a two-scoring system to award up to 20 points to the IOTA participant based on its performance on the OPTN organ offer acceptance rate ratio. Under this two-scoring system, we would determine two separate scores for an IOTA participant: an ''achievement score'' reflecting its current level of performance, and an ''improvement score'' reflecting changes in its performance over time. We propose that the IOTA participant would be awarded points equal to the higher of the two scores, up to a maximum of 20 points. We believe that this approach would recognize both high achievement among high performing IOTA participants as well as IOTA participants that make marked improvement in their performance. We believe that average or low-performing IOTA participants would likely require multiple years of transformation to catch up with those who have a high organ offer acceptance rate ratio.

For achievement scoring, we propose that points earned would be based on the IOTA participants' performance on the organ offer acceptance rate ratio ranked against a national target, inclusive of all eligible kidney transplant hospitals, both those selected and not selected as IOTA participants. Currently, there is a large disparity in organ offer acceptance ratio performance. As previously noted, a 2020 national registry study found that the probability of receiving a deceased donor kidney transplant within 3 years of waiting list placement varied 16-fold between different kidney transplant hospitals across the U.S.[220] Large variations were still present between kidney transplant hospitals that utilized the same OPO.[221] The probability of transplant was significantly associated with transplant hospitals' offer acceptance rates.[222]

We propose that achievement scoring points be awarded based on the national quintiles, as outlined in Table 6. Utilizing quintiles aligns with the calculation of the upside and downside risk payments in relation to the final performance score, as detailed in section III.C.6.c.(2). of this proposed rule, where average performance yields half the number of points. The scoring is normalized, meaning an average performing IOTA participant earns 10 points out of 20, 50 percent of the total possible points. We recognize that there is an upper limit to the benefits of efficiency, and quintiles combine the highest 20 percent of performers in a point band. Due to the current disparity among kidney transplant hospitals on this metric, we do not expect every IOTA participant to reach top-level performance.

We propose the following Organ Offer Acceptance Rate Achievement point allocation for IOTA participants, as illustrated in Table 6:

- IOTA participants in the 80th percentile and above, 20 points.
- IOTA participants in the 60th to below the 80th percentile of performers, 15 points.
- IOTA participants in the 40th to the 60th percentile of performers, 10 points.
- IOTA participants in the 20th to below the 40th percentile of performers, 6 points.
- IOTA participants who are below the 20th percentile of performers, 0 points.

TABLE 6: ORGAN OFFER ACCEPTANCE RATE ACHIEVEMENT SCORING

Performance Relative to National Ranking	Lower Bound Condition	Upper Bound Condition	Points Earned
80th Percentile relative to target OR for comparison	Equals 80th percentile	Greater than 80th percentile	20
60th Percentile	Equals 60th percentile	Less than 80th percentile	15
40th Percentile	Equals 40th percentile	Less than 60th percentile	10
20th Percentile	Equals 20th percentile	Less than 40th percentile	6
20th Percentile	N/A	Less than 20th percentile	0

We considered the approach used by the MPSC, that would yield maximum points if transplant hospitals have at least a .35 organ offer acceptance rate ratio. However, we do not believe that this approach fits with the IOTA Model's goals. MPSC metrics are more focused on highlighting and improving performance for the lowest performers, whereas the model seeks to improve performance across the board, not just avoid poor performance.

For improvement scoring, we propose that points earned would be based on the IOTA participants' performance on organ offer acceptance rate ratio during a PY relative to their performance during the third baseline year for the PY that is being measured. We propose to use the same baseline year definition used for participant eligibility, as described in section III.C.3 of this proposed rule, including the rationale for doing so. We separately propose to calculate an ''improvement benchmark rate,'' defined as 120 percent of the IOTA participants' performance on the organ offer acceptance rate ratio during the third baseline year for each PY. We would award points by comparing the IOTA participant's organ offer acceptance rate ratio during the PY to the IOTA participant's improvement benchmark rate to determine the improvement scoring points earned. Specifically:

- IOTA participants whose organ offer acceptance rate ratio during a PY

[220] King, K.L., Husain, S.A., Schold, J.D., Patzer, R.E., Reese, P.P., Jin, Z., Ratner, L.E., Cohen, D.J., Pastan, S.O., & Mohan, S. (2020). Major Variation across Local Transplant Centers in Probability of Kidney Transplant for Wait-Listed Patients. *Journal of the American Society of Nephrology, 31*(12), 2900–2911. *https://doi.org/10.1681/ASN.2020030335*.

[221] King, K.L., Husain, S.A., Schold, J.D., Patzer, R.E., Reese, P.P., Jin, Z., Ratner, L.E., Cohen, D.J., Pastan, S.O., & Mohan, S. (2020). Major Variation across Local Transplant Centers in Probability of Kidney Transplant for Wait-Listed Patients. *Journal of the American Society of Nephrology, 31*(12), 2900–2911. *https://doi.org/10.1681/ASN.2020030335*.

[222] Ibid.

is at or above the improvement benchmark rate would receive 12 points.

- IOTA participants whose organ offer acceptance rate ratio during a PY is at or below the organ offer acceptance rate ratio during the third baseline year for that respective PY would receive no points.
- IOTA participants whose organ offer acceptance rate ratio during a PY is greater than the organ offer acceptance rate ratio during the third baseline year for that respective PY, but less than the improvement benchmark rate, would earn a maximum of 12 points in accordance with equation 1 to paragraph (c)(1)(ii)(B)(*1*) of § 512.426.

We propose using equation 1 to paragraph (c)(1)(ii)(B)(*1*) of § 512.426 to mirror the methodology used in the Hospital Value Based Purchasing (VBP) Program, with the only modification being the number of points available for this metric. Equation 3 would also allow for a maximum of 12 points to be earned by IOTA participants whose organ offer acceptance rate ratio during the PY is greater than the baseline year organ offer acceptance rate ratio but less than the improvement benchmark rate. We did not want the improvement score to be worth more than, or equal to, the achievement score, as proposed for the organ offer acceptance rate ratio performance scoring, so as to reserve the highest number of points (15 points) for top performers in the metric.

Once both the achievement score and the improvement score are calculated, we propose comparing the two scores and applying the higher of the two values as the performance score or points earned (of 20 possible points) for the organ offer acceptance rate ratio metric within the efficiency domain.

We considered setting the improvement benchmark rate to be 200 percent of the IOTA participant's third baseline year for a given PY to measure performance on the organ offer acceptance rate ratio. The scoring structure would be the same, with 12 or 0 points to be awarded depending on whether the benchmark is met. However, we believed this would be too strict and risk penalizing already high-achieving IOTA participants.

We considered simplifying the performance scoring for the organ offer acceptance rate ratio metric within the efficiency domain by only awarding performance points based on the proposed achievement scoring methodology, rather than also calculating an improvement score for the IOTA participant and comparing the scores. However, given the variation that is present amongst kidney transplant hospitals, we believed it might be difficult for some IOTA participants to achieve top tier points for the first two model PYs. Thus, incorporating an improvement scoring method would ensure that IOTA participants are still rewarded for improvements made towards the efficiency domain goal.

We considered using the scoring method proposed for the post-transplant outcomes metric within the quality domain, as described in section III.C.5.e.(1).(b). of this proposed rule, as it would award full points if the hazard ratio or confidence interval of the metric includes the number one or higher. We believe this scoring method would honor the intent of the organ offer acceptance rate ratio metric, which is to determine if an IOTA participant is accepting more organs than expected. However, given the variation in performance on this metric across all kidney transplant hospitals, we believe improvement opportunities exist in this metric. We also believe that our proposed approach rewards both achievement and improvements and is a more rigorous scoring methodology.

We considered a continuous scoring range from zero to 15, where IOTA participants may earn a score of any point value instead of bands. We believe a continuous scoring range could provide more flexibility for IOTA participants and greater variety of scores. However, we believe grading using bands provides a more favorable scoring system for IOTA participants by grouping performance. We also recognize there is diminishing marginal efficiency for higher and higher organ offer acceptance rate ratios.

We considered using the lower and upper bounds of the offer acceptance odds ratio within a confidence interval, like we are proposing in the quality domain for post-transplant outcomes, as described in section III.C.5.e.(1).(b). of this proposed rule. However, the organ offer acceptance rate ratio metric, unlike post-transplant outcomes, has wider disparity in performance than in post-transplant outcomes. We believe that there is a clear benefit to patients and the transplantation ecosystem overall by continuing to increase performance on this metric and promoting better performance than the national average. Under this alternative, IOTA participants would be evaluated based on whether the lower bound, acceptance ratio, and upper bound all crossed 1. Doing so would indicate the IOTA participant's true offer acceptance ratio with 95 percent probability. We are not proposing this approach, however, as our analyses using SRTR data indicate that the majority of kidney transplant hospitals had either all three bounds cross 1 or all three never cross 1. Thus, scoring would largely not have differed from utilizing the offer acceptance ratio alone.

Finally, we also considered stratifying offer acceptance by KDRI status, with different score targets based on KDRI status ranges, such as KDRI of less than 1.05, between 1.05 and 1.75, and more than 1.75. We believe this scoring method may potentially prevent IOTA participants from narrowing their criteria to only receive selected offers. However, we believe that it is already risk adjusted for organ status inherently in the measure because only organs that are ultimately transplanted are counted in the denominator.

We seek comment on our proposed organ offer acceptance rate ratio performance scoring methodology for purposes of assessing efficiency domain performance for each IOTA participant, including on the achievement and improvement score calculation and point allocation method. We also seek comments on alternatives considered.

e. Quality Domain

We propose to define ''quality domain'' as the performance assessment category in which CMS assesses the IOTA participant's performance using a performance measure and quality measure set focused on improving the quality of transplant care, as described in section III.C.5.e. of this proposed rule. We propose that performance on the quality domain would be worth up to 20 points out of the proposed 100 points. The quality domain is focused on monitoring post-transplant care and quality of life for IOTA transplant patients.

Our goal for the quality domain within the IOTA Model is to achieve acceptable post-transplant outcomes while incentivizing increased kidney transplant volume. We believe that transplant hospital accountability for patient-centricity and clinical outcomes continues post-transplantation. While transplant outcomes have historically received the most attention, often at the exclusion of other factors, we seek to encourage a better balance in the system to offer the benefits of transplant to more patients. Therefore, we are proposing to include one post-transplant outcome measure, as described in section III.C.5.e.(1). of this proposed rule, and a quality measure set that includes two patient-reported outcome-based performance measures (PRO–PM) and one process measure, as described in section III.C.5.e.(2). of this proposed rule.

(1) Post-Transplant Outcomes

We propose using an unadjusted rolling ''composite graft survival rate,'' defined as the total number of functioning grafts relative to the total number of adult kidney transplants performed, as described in section III.C.5.e.(1).(a). of this proposed rule, to assess IOTA participant performance on post-transplant outcomes. In this measure, the numerator (observed functioning grafts) and denominator (number of kidney transplants completed) would increase each PY of the IOTA Model to include a cumulative total.

Over the past few decades, advances in immunosuppressive therapies, surgical techniques, and organ preservation methods have resulted in significant improvements in kidney transplantation outcomes.[223] According to the OPTN, the overall 1-year survival rate for kidney transplantation recipients in the United States is over 90 percent, and the 5-year survival rate is around 75 percent. However, even with the advances that have been made to improve kidney outcomes, the success of kidney transplantation is still dependent upon factors such as the age and health of the donor and recipient, the presence of comorbidities (for example, diabetes), and the effectiveness of the immunosuppressive regimen. Kidney transplant outcomes can also be affected by possible post-transplant complications, including infection, cardiovascular disease, and kidney failure.[224]

More recently, CMS received feedback from transplant hospitals, patient advocacy groups, and transplant societies, including on the recent rule making (''Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction,'' 83 FR 47686), that the 1-year measure was causing transplant centers to be risk averse about the patients and organs they would transplant while being simultaneously topped out (83 FR 47706).[225] Notably, even the lowest ranked programs, as measured by the SRTR, achieved a result of 90 percent of transplanted patients have a functioning graft at one year.[226]

To safeguard patient outcomes under the IOTA Model, we are proposing to include this measure as a checkpoint. Because there is significant variation in post-transplant outcomes across kidney transplant hospitals, we believe the IOTA Model should promote improvement in outcomes for the benefit of attributed patients. We also believe that this measure would build upon, and complement, existing OPTN and SRTR measures to the maximum extent possible. Additionally, we believe that this approach could be applied with minimal adaptation to other organs were they to be added to the model through future rulemaking. Furthermore, we believe that this measure would enhance patient understanding of clinically important post-transplant outcomes beyond existing 90-day, 1-year and 3-year post transplant outcomes.

We considered measuring post-transplant outcomes using SRTR's methodology at 90 days,[227] and constructing 5-year and 10-year post-transplant measures. However, we did not select these measures because post-transplant outcomes are already measured at 90-days by SRTR. Additionally, because the IOTA Model as proposed spans only 6 years, we did not believe we could appropriately measure post-transplant outcomes at 5 or 10 years.

We considered constructing an ongoing post-transplant outcome measure that would continuously evaluate post-transplant outcomes at 1-year throughout the model performance period of the IOTA Model. In this measure the numerator (observed graft failures) and denominator (number of transplants completed) would increase each PY of the model to a cumulative total. For example, in PY 1 of the model an IOTA participant could have five 1-year observed graft failures and complete 20 transplants, resulting in a graft failure rate of 0.25. In PY 2 of the model, the same IOTA participant could have eight 1-year observed graft failures and complete 30 transplants. To calculate the IOTA participant's graft failure rate for PY 2 of the model, we would divide the cumulative total of 13 1-year observed graft failures by the cumulative total of 50 completed transplants. However, we believed it was important to measure post-transplant outcomes in terms of graft survival rather than in terms of graft failure. We acknowledge that for the purposes of measuring graft survival using OPTN data, use of either concept would generate the same outcome measurement because OPTN data identify graft status as either functioning or failed. However, we aim to convey the importance of ongoing management to preserve the health of the transplanted graft and the health and quality of life of the attributed patients.

We considered constructing a continuous patient survival measure that would evaluate patient survival throughout the entirety of the IOTA Model. Similar to the considered measure mentioned in the previous paragraph, the numerator (number of patients alive) and denominator (number of received kidney organ offers) would increase each PY of the model to a cumulative total. For the denominator, we considered only including organ offers where the sequence number was less than 100 or less than 50. In other words, under that rationale we would only include offers that came within a certain point of time that could have potentially benefited the patient or should not have been turned down. We believe that this type of measure would not disincentivize waitlisting and could potentially increase equity within this population. Additionally, we believe that this type of measure would indirectly encourage living donor transplants because those would only hit the numerator (number of people alive) but not the denominator (number of kidney organ offers received). However, we believe this measure

[223] Stewart, D.E., Garcia, V.C., Rosendale, J.D., Klassen, D.K., & Carrico, B.J. (2017). Diagnosing the Decades-Long Rise in the Deceased Donor Kidney Discard Rate in the United States. *Transplantation, 101*(3), 575–587. *https://doi.org/10.1097/tp0000000000001539*;. Vinson, A., Kiberd, B.A., & Karthik Tennankore. (2021). *In Search of a Better Outcome: Opting Into the Live Donor Paired Kidney Exchange Program. 8,* 205435812110174–205435812110174. *https://doi.org/10.1177/20543581211017412*; Shepherd, S., & Formica, R. N. (2021). *Improving Transplant Program Performance Monitoring. 8*(4), 293–300. *https://doi.org/10.1007/s40472-021-00344-z.*

[224] Gioco, R., Sanfilippo, C., Veroux, P., Corona, D., Privitera, F., Brolese, A., Ciarleglio, F., Volpicelli, A., & Veroux, M. (2021). Abdominal wall complications after kidney transplantation: A clinical review. *Clinical Transplantation, 35*(12), e14506. *https://doi.org/10.1111/ctr.14506*; Wei, H., Guan, Z., Zhao, J., Zhang, W., Shi, H., Wang, W., Wang, J., Xiao, X., Niu, Y., & Shi, B. (2016). Physical Symptoms and Associated Factors in Chinese Renal Transplant Recipients. *Transplantation Proceedings, 48*(8), 2644–2649. *https://doi.org/10.1016/j.transproceed.2016.06.052*; Mehrabi, A., Fonouni, H., Wente, M., Sadeghi, M., Eisenbach, C., Encke, J., Schmied, B.M., Libicher, M., Zeier, M., Weitz, J., Büchler, M.W., & Schmidt, J. (2006). Wound complications following kidney and liver transplantation. *Clinical Transplantation, 20*(s17), 97–110. *https://doi.org/10.1111/j.1399-0012.2006.00608.x.*

[225] Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction (September, 20, 2018) *https://www.federalregister.gov/documents/2018/09/20/2018-19599/medicare-and-medicaid-programs-regulatory-provisions-to-promote-program-efficiency-transparency-and.*

[226] Scientific Registry of Transplant Recipients. Request for Information. Requested on 05/02/2023. *https://www.srtr.org./.*

[227] *Mpsc-enhance-transplant-program-performance-monitoring-system_srtr-metrics.pdf* (n.d.). Retrieved December 28, 2022, from *https://optn.transplant.hrsa.gov/media/qfuj3osi/mpsc-enhance-transplant-program-performance-monitoring-system_srtr-metrics.pdf.*

would be somewhat duplicative of other parts of the model where we are already evaluating organ offer acceptance. We also chose not to propose this measure due to logistical concerns, and believed it could be difficult to determine how many people were offered a specific organ and determining what an appropriate sequence number cutoff should be.

We considered measuring estimated glomerular filtration rate (eGFR) at the 1-year anniversary of the date of transplant. Glomerular filtration rate (GFR) is a way to assess renal function, and eGFR is the test used to assess renal function in primary clinical care.[228] Despite the fact that studies indicate eGFR's potential as a reliable predictor of long-term post-transplant prognosis, our goal is to adopt a measure that resonates more with the transplant community's evaluation of post-transplant outcomes.[229] We recognize that the equation for calculating eGFR was revised in 2021 to not include race, but we still have some concerns over the potential for bias and inaccurate results and the limitations that still exist with the updated equation and did not feel it was appropriate to propose.[230]

We considered constructing several hospital-based post-transplant outcome measures such as those that measure: the number of days spent out of the hospital post-transplant, how many days spent at home post-transplant before returning to work, and number of hospital readmissions post-transplant. However, we do not want to penalize the use of moderate-to-high KDPI kidneys, as we recognize that utilizing these organs carries an increased risk of transplant recipient hospitalizations. Additionally, we had concerns over how we would assess and measure this type of metric.

We considered proposing a phased-in approach to measuring post-transplant outcomes, in which no post-transplant outcome metrics would be included until PY 3 of the model. In this alternative methodology, the quality domain for the first two PYs would only include our proposed quality measure set, as described in section III.C.5.e.(2). of this proposed rule. Starting PY 3 of the model, IOTA participants would be evaluated on two post-transplant outcome measures (SRTR's 1-year post-transplant outcome conditional on 90-day survival measure and 3-year post-transplant outcome measure) in addition to our proposed quality measure set. This approach incorporates a time delay, allowing us to assess the post-transplant outcomes of IOTA participants using SRTR's measures. Because we believed it was critical to include a post-transplant measure from the onset of the model to check for unintended consequences throughout the entirety of the model performance period, we did not believe this alternative was appropriate to propose.

We also considered using SRTR's new ''1-year post-transplant outcome conditional on 90-day graft survival'' measure and including a 3-year post-transplant outcome measure, such as the one currently used by SRTR. We also considered constructing our own 3-year post-transplant outcome measure conditional on 1-year survival. However we chose not to propose SRTR's conditional 1-year or 3-year post-transplant outcome measures or our own measure for the following reasons: (1) because SRTR's conditional 1-year metric has a 2.5 year lookback period, it would require us to evaluate IOTA participants on post-transplant outcomes prior to starting the model for at least the first two PYs; (2) because SRTR does not currently have a 3-year conditional post-transplant outcome measure, we would not be in alignment with SRTR if we constructed our own; (3) including SRTR's 3-year post-transplant outcome measure would include time outside of the model for at least the first three PYs and we want to evaluate IOTA participants based on their performance within the model; and (4) we recognize there may be some logistical issues and difficulty in measuring performance in that time. We may consider incorporating a 3-year post-transplant outcome measure into the model in the future, through rulemaking.

We seek public comment on our proposal to evaluate IOTA participants on post-transplant outcomes using our new composite graft survival rate metric, as well as on the alternatives we considered. We are also interested in public comment on how we may be able to use OPTN data to characterize different clinical manifestations of graft survival, as we understand that not all surviving grafts are clinically equivalent or have the same impact on the patient and graft health. We would further be interested to hear from the public on which factors involved in graft survival are modifiable by the care team.

(a) Calculation of Metric

We propose that for each model PY, CMS would calculate a composite graft survival rate for each IOTA participant, as defined in section III.C.5.e.(1). of this proposed rule, to measure performance in the quality domain as described in section III.C.5.e. of this proposed rule.

We propose to use our own unadjusted composite graft survival rate equation to evaluate post-transplant outcomes. We propose to calculate the composite graft survival rate by taking the total number of functioning grafts an IOTA participant has and dividing that by the total number of kidney transplants furnished to patients 18 years of age or older at the time of the transplant in PY 1 and all subsequent PYs as specified in Equation 1 to paragraph (b)(1) of § 512.428 to evaluate post-transplant outcomes during the IOTA Model performance period.

For example, if in PY 1 of the model, an IOTA participant had 20 observed functioning grafts and furnished 25 kidney transplants to patients 18 years of age or older at the time of transplant, the composite graft survival rate for that IOTA participant would be 0.8 (20 from PY 1 divided by 25 from PY 1). Continuing this example, for PY2 of the model if the same IOTA participant had 30 observed functioning grafts and furnished 35 kidney transplants to patients 18 years of age or older at the time of transplant, and two functioning kidney grafts failed from PY 1, CMS would calculate its composite graft survival rate for PY 2 as follows. CMS would divide the cumulative total of 48 observed functioning grafts (30 from PY 2 + 20 from PY 1 − 2 from PY 1) by the cumulative total of 60 completed kidney transplants (35 from PY 2 + 25 from PY 1), resulting in a composite graft survival rate of 0.8 (48 divided by 60).

In the proposed equation, the numerator (number of functioning grafts) is defined as the total number of living adult kidney transplant patients with a functioning graft. The numerator,

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[228] Mayne, T.J., Nordyke, R.J., Schold, J.D., Weir, M.R., & Mohan, S. (2021). Defining a minimal clinically meaningful difference in 12-month estimated glomerular filtration rate for clinical trials in deceased donor kidney transplantation. *Clinical Transplantation, 35*(7), e14326. *https://doi.org/10.1111/ctr.14326*.

[229] Ibid; Wu, J., Li, H., Huang, H., Wang, R., Wang, Y., He, Q., & Chen, J. (2010). Slope of changes in renal function in the first year post-transplantation and one-yr estimated glomerular filtration rate together predict long-term renal allograft survival. *Clinical Transplantation, 24*(6), 862–868. *https://doi.org/10.1111/j.1399-0012.2009.01186.x;* Schold, J.D., Nordyke, R.J., Wu, Z., Corvino, F., Wang, W., & Mohan, S. (2022). Clinical events and renal function in the first year predict long-term kidney transplant survival. *Kidney360,* 10.34067/KID.0007342021. *https://doi.org/10.34067/kid.0007342021;* Hariharan, S., Mcbride, M.A., Cherikh, W.S., Tolleris, C.B., Bresnahan, B.A., & Johnson, C.P. (2002). Post-transplant renal function in the first year predicts long-term kidney transplant survival. *Kidney International, 62*(1), 311–318. *https://doi.org/10.1046/j.1523-1755.2002.00424.x*.

[230] Majerol, M., & Hughes, D.L. (2022, July 5). CMS Innovation Center Tackles Implicit Bias. *Health Affairs*. Retrieved January 16, 2024, from *https://www.healthaffairs.org/content/forefront/cms-innovation-center-tackles-implicit-bias*.

functioning grafts, would exclude grafts that have failed, as defined by SRTR. SRTR counts a graft as failed when follow-up information indicates that one of the following occurred before the reporting time point: (1) graft failure (except for heart and liver, when re-transplant dates are used instead); (2) re-transplant (for all transplants except heart-lung and lung); or 3) death.[231] OPTN follow-up forms are used to identify graft failure and re-transplant dates.[232] We also propose to use OPTN adult kidney transplant recipient follow-up forms [233] to identify graft failure and re-transplant dates for all transplant furnished to kidney transplant patients 18 years of age or older at the time of the transplant. In the proposed equation, we note that the numerator and denominator would not be limited to the attributed IOTA transplant patients. By this, we mean that it could include IOTA transplant patients who have been de-attributed from an IOTA participant due to transplant failure. We believe that IOTA participants could improve on this metric by working with IOTA collaborators to coordinate post-transplant care.

We considered incorporating a risk adjustment methodology to our proposed composite graft survival equation, such as the one used by SRTR for 1-year post-transplant outcomes conditional on 90-day survival or constructing our own. While we recognize that risk adjustment methodologies may help account for patient and donor traits, we could not find a risk adjustment approach that has consensus agreement within the kidney transplant community. We also believe that our proposed measure is inherently risk adjusted as it only counts organs that are ultimately transplanted to patients 18 years of age or older by a kidney transplant hospital.

We invite public comment on our proposed methodology to calculate post-transplant outcomes in the IOTA Model, and on alternatives considered. Although we are proposing an unadjusted composite graft survival rate to measure post-transplant outcomes, we are interested in comments on whether risk risk-adjustments are necessary, and which ones, such as donor demographic characteristics (race, gender, age, disease condition, geographic location), would be significant and clinically appropriate in the context of our proposed approach.

(b) Calculation of Points

As described in section III.C.5.e. of this proposed rule, performance on the quality domain would be worth up to 20 points. Within the quality domain, we propose that the composite graft survival rate would account for 10 of the 20 allocated points. We propose that the points earned would be based on the IOTA participants' performance on the composite graft survival rate metric ranked against a national target, inclusive of all eligible kidney transplant hospitals, both those selected and not selected as IOTA participants. We believe that using percentiles would create even buckets of scores among the continuum of IOTA participants.

We propose that points would be awarded based on the national quintiles, as outlined in Table 7, such that IOTA participants that perform—

- At or above the 80th percentile would earn 10 points;
- In the 60th percentile to below the 80th percentile would earn 8 points;
- In the 40th to below the 60th percentile would earn 5 points;
- In the 20th percentile to below the 40th percentile would earn 3 points; and
- Below the 20th percentile would receive no points for the composite graft survival rate.

TABLE 7: COMPOSITE GRAFT SURVIVAL RATE SCORING

Performance Relative to Target	Points Earned
80^{th} Percentile $\leq$	10
$60^{th} \leq$ and $< 80^{th}$ Percentile	8
$40^{th} \leq$ and $< 60^{th}$ Percentile	5
$20^{th} \leq$ and $< 40^{th}$ Percentile	3
$< 20^{th}$ Percentile	0

Utilizing quintiles aligns with the calculation of the upside and downside risk payments in relation to the final performance score as detailed in section III.C.6.c.(2). of this proposed rule, where average performance yields half the number of points. The scoring is normalized, meaning an average performing IOTA participant earns 5 points out of 10, or about 50 percent of possible points. We recognize that there is an upper limit to the benefits of efficiency, and quintiles combine the highest 20 percent of performers in a point band. Due to the current disparity among kidney transplant hospitals, we do not expect every IOTA participant to reach top-level performance on this metric.

We considered a strategy similar to the proposed organ offer acceptance methodology which would apply a two-scoring system in which we would determine an achievement score and improvement score and award the point equivalent to the higher value between the two scores. We also considered proposing just an improvement score, in which we would evaluate IOTA participants' performance on composite graft survival during a PY relative to their performance the previous CY. We considered both approaches because we recognize that if an IOTA participant does not do well one year in our proposed methodology, that it may be difficult for it to improve during the model performance period. However, we chose not to propose either of these other methodologies (achievement and improvement or just improvement scoring) because we had concerns over

[231] *Technical Methods for the Program-Specific Reports.* (n.d.). *Www.srtr.org.* Retrieved December 3, 2022, from *https://www.srtr.org/about-the-data/technical-methods-for-the-program-specific-reports/* ; OPTN. (2022). *OPTN Enhanced Transplant Program Performance Metrics. https://optn.transplant.hrsa.gov/media/r5lmmgcl/mpsc_performancemetrics_3242022b.pdf.*

[232] *Technical Methods for the Program-Specific Reports.* (n.d.). *Www.srtr.org.* Retrieved December 3, 2022, from *https://www.srtr.org/about-the-data/technical-methods-for-the-program-specific-reports/.*

[233] *https://unos.org/wp-content/uploads/Adult-TRF-Kidney.pdf.*

our ability to measure improvement year over year due to potentially small numbers.

We seek public comment on the proposed point allocation and calculation methodology for post-transplant outcomes within the quality domain for the IOTA Model and alternatives considered.

(2) Quality Measure Set

We propose to select and use quality measures to assess IOTA participant performance in the quality domain. Performance on the proposed IOTA Model quality measure set would be used to assess the performance of an IOTA participant on aspects of care that we believe contribute to a holistic and patient-centered journey to receiving a kidney transplant.

We propose the following three measures for inclusion in the IOTA Model quality measure set: (1) CollaboRATE Shared Decision-Making Score (CBE ID: 3327), (2) Colorectal Cancer Screening (COL) (CBE ID: 0034), and (3) the 3-Item Care Transition Measure (CTM–3) (CBE ID: 0228).[234] [235] [236] The quality measures that we are proposing share common features. We are proposing measures that have been or are currently endorsed by the CMS Consensus-Entity (CBE) through the CMS Consensus-Based Process. This ensures that the measures proposed have been assessed against established evaluation criteria of importance, acceptability of measure properties, feasibility, usability, and competing measures.[237] Our proposed measure set is patient-centered, reflecting areas that we have heard from patients are important and for which there is significant variation in performance among transplant hospitals. We are proposing measures that would incentivize improvements in care that we would otherwise not expect to improve based on the financial incentives in the model alone. We are also proposing a measure set that would allow us to make a comprehensive assessment of post-transplant outcomes. The composite graft survival rate that we are proposing in section III.C.5.e.(1). of this proposed rule would provide an essential, albeit limited, assessment of the success of a kidney transplant. Finally, we are proposing measures that we believe would incentivize improvement in aspects of post-transplant care that are important to patients and modifiable by IOTA participants.

On March 2, 2023, Jacobs et al. published *Aligning Quality Measures across CMS—The Universal Foundation,* which describes CMS leadership's vision for a set of foundational quality measures known as the Universal Foundation. This measure set would be used by as many CMS value-based and quality programs as possible, with other measures added based on the population or healthcare setting.[238] CMS selected measures for the Universal Foundation that are meaningful to a broad population, reduce burden by aligning measures, advance equity, support automatic and digital reporting, and have minimal unintended consequences.[239]

We considered only including two measures in the initial quality measure set and pre-measure development because we were concerned about the potential added reporting burden placed on IOTA participants. However, we chose to propose three measures and pre-measure development because we want to use them to incentivize and improve patient care. We seek additional feedback on which of the proposed measures have the highest potential to impact changes in behavior, while minimizing provider burden.

We also considered only including COL in the quality measure set and allotting this measure 4 points, with the remaining 16 points allotted to the composite graft survival rate. It is worth noting that if we choose fewer measures, then we propose allocating the points accordingly within the remaining measures.

We considered several alternative measures for the quality domain performance assessment. We considered the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey because hospitals are already required to report that survey in the Hospital VBP Program, thereby reducing or limiting burden to IOTA participants burden since it is already in use. We are not proposing the HCAHPS measure for the IOTA Model because HCAHPS data is based on survey results from a random sample of adult patients across medical conditions. We believe that the HCAHPS would present sample size issues for purposes of calculation.

We considered the Gains in Patient Activation Measure (PAM®) (CBE ID: 2483). The PAM® measure is being used in the voluntary KCC Model and was included on the 2022 Measures Under Consideration (MUC) List for the ESRD Quality Incentive Program (QIP) and MIPS.[240] We considered whether the PAM® Measure could encourage IOTA participants and IOTA Collaborators, as defined in section III.C.11.d. of this proposed rule, to activate IOTA waitlist patients to work in collaboration with IOTA participants to complete requirements to maintain active waitlist status; however, we were unable to locate any peer-reviewed literature to support this hypothesis.

We also considered the Depression Remission at 12 Months measure (CBE ID: 0710e). Studies have shown that depression and anxiety are common amongst people on dialysis and suggested that incorporating patient reported outcome measures (PROs) that focus on depression can improve health-related quality of life in patients with ESRD.[241] One study found that, at the time of kidney evaluation, over 85 percent of patients exhibited at least minimal depressive symptoms and that patients with depressive symptoms were less likely to gain access to the waitlist.[242] Although the waitlist offers

[234] *collaboRATE.* (2019). Glyn Elwyn. *http://www.glynelwyn.com/collaborate.html.*

[235] *Colorectal Cancer Screening—NCQA.* (2018). NCQA. *https://www.ncqa.org/hedis/measures/colorectal-cancer-screening/ https://www.ncqa.org/hedis/measures/colorectal-cancer-screening/.*

[236] *THE NATIONAL QUALITY FORUM Specifications for the Three-Item Care Transition Measure-CTM–3.* (n.d.). Retrieved May 28, 2023, from *https://mhdo.maine.gov/_pdf/NQF_CTM_3_%20Specs_FINAL.pdf.*

[237] Supplemental Material to the CMS Measures Management System (MMS) Hub CMS Consensus-Based Entity (CBE) Endorsement and Maintenance. (2022). *https://www.cms.gov/files/document/blueprint-nqf-endorsement-maintenance.pdf.*

[238] Jacobs, D. B., Schreiber, M., Seshamani, M., Tsai, D., Fowler, E., & Fleisher, L.A. (2023). Aligning quality measures across CMS—the Universal Foundation. *New England Journal of Medicine, 388*(9), 776–779. *https://doi.org/10.1056/nejmp2215539.*

[239] Jacobs, D.B., Schreiber, M., Seshamani, M., Tsai, D., Fowler, E., & Fleisher, L.A. (2023). Aligning quality measures across CMS—the Universal Foundation. *New England Journal of Medicine, 388*(9), 776–779. *https://doi.org/10.1056/nejmp2215539.*

[240] *Pre-Rulemaking | The Measures Management System.* (n.d.). *Mmshub.cms.gov.* Retrieved May 12, 2023, from *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/overview.*

[241] Feroze, U., Martin, D., Kalantar-Zadeh, K., Kim, J.C., Reina-Patton, A., & Kopple, J.D. (2012). Anxiety and depression in maintenance dialysis patients: Preliminary data of a cross-sectional study and brief literature review. *Journal of Renal Nutrition, 22*(1), 207–210. *https://doi.org/10.1053/j.jrn.2011.10.009;* Mclaren, S., Jhamb, M., & Unruh, M. (2021). Using Patient-Reported Measures to Improve Outcomes in Kidney Disease. *Blood Purification,* 1–6. *https://doi.org/10.1159/000515640;* Cukor, D., Donahue, S., Tummalapalli, S.L., Bohmart, A., & Silberzweig, J. (2022). Anxiety, comorbid depression, and dialysis symptom burden. *Clinical Journal of the American Society of Nephrology, 17*(8), 1216–1217. *https://doi.org/10.2215/cjn.01210122.*

[242] Chen, X., Chu, N.M., Basyal, P.S., Vihokrut, W., Crews, D., Brennan, D.C., Andrews, S.R., Vannorsdall, T.D., Segev, D.L., & McAdams-DeMarco, M. A. (2022). Depressive symptoms at kidney transplant evaluation and access to the kidney transplant waitlist. *Kidney International Reports, 7*(6), 1306–1317. *https://doi.org/10.1016/j.ekir.2022.03.008.*

some hope to patients, being waitlisted for a kidney transplant is also psychologically distressing, with patients reporting disillusionment, moral distress, unmet expectations, increasing vulnerability, and deprivation.[243] These factors are likely contributors to high rates of stress and anxiety observed among waitlisted patients.[244] The conditions of participation (CoPs) for transplant hospitals require that prospective transplant candidates receive a psychosocial evaluation prior to placement on a waitlist (42 CFR part 482.90(a)(1)), if possible, and OPTN bylaws specify that transplant hospitals must include team members to coordinate a transplant candidate's psychosocial needs; however, neither the CoP nor the OPTN bylaws require specific assessment of, or intervention into, patients' behavioral health. The ESRD QIP measure set includes the Clinical Depression Screening and Follow-Up measure; however, performance on the measure requires only documentation that an attempt at screening and follow up was made.[245] Additionally, this measure is already being used in the KCC Model.

While we understand the importance of including measures focused on depression, we believe that IOTA participants may have limited experience diagnosing and treating depression and may struggle to make referrals due to limited behavioral health providers. We also believe that this measure may be duplicative with other policies in this model that strive to improve the health and post-transplant outcomes of attributed patients. Additionally, based on the KCC Model experience, the Depression Remission measure is operationally complex due to the 10-month reporting period and novel collection and reporting processes. We believe that IOTA participants would experience similar challenges due to the mandatory nature of the model and unfamiliarity with reporting quality measure data to the Innovation Center.

We considered the Depression Remission at 12 Months measure (CBE ID: 0710e) because major depression is prevalent in the dialysis population and most kidney transplant recipients spend some time on a dialysis modality.[246] Depression measures are included in the Universal Foundation because successfully treating depression can improve physical health outcomes, in addition to behavioral health outcomes.[247] A depression measure would align with the behavioral health domain of Meaningful Measures 2.0. We considered a depression remission measure over a depression screening measure because we believed a depression remission measure would incentivize IOTA participants to work with the other clinicians and providers involved in the care of attributed patients to resolve or improve the depressive symptoms rather than only identifying them. Our review of the literature found that presence of behavioral health symptoms affected the ability of patients to get on the kidney transplant waitlist, but did not affect likelihood of receiving a kidney transplant.[248] We are not proposing the Depression Remission at 12 Months Measure because we were unable to locate any publications that found depression remission affected access to a kidney transplant. We also chose not to propose this type of measure because the IOTA Model does not target pre-waitlist patients for attribution to model participants. We also believe that IOTA participants may have limited experience in diagnosis and treating depression and may struggle to make referrals due to limited behavioral health providers. Additionally, behavioral health management is not under the purview of a kidney transplant hospital that might see a kidney transplant waitlist patient perhaps only a handful of times, but may be more appropriate for the patient's nephrologist or dialysis center.

We seek comment on our proposed quality measure set that includes two PRO–PMs (CollaboRATE Shared Decision-Making Score and 3-Item Care Transition Measure) and one process measure (Colorectal Cancer Screening) for purposes of measuring performance in the quality domain. We also seek comment on alternative quality measures considered.

(a) Quality Measure Set Selection, Reporting and Changes

As proposed in section III.C.5.e.(2). of this proposed rule, we are proposing that CMS select and use quality measures to assess IOTA participant performance in the quality domain. We propose that each PY, IOTA participants would be required to report quality measure data during survey and reporting windows to CMS in a form and manner, and at times, established by CMS. We also propose that, where applicable, IOTA participants would be required to administer any surveys or screenings relevant to the quality measures selected for inclusion in the IOTA Model to attributed patients. We propose to define ''survey and reporting windows'' as two distinct periods where IOTA participants would be required to administer a quality measure-related survey or screening to attributed patients or submit attributed patient responses to CMS pursuant to § 512.48(b)(2)(ii). We propose that CMS would notify, in a form and manner as determined by CMS, IOTA participants of the survey and reporting window for applicable quality measures by the first day of each PY.

We propose that CMS would use future rulemaking to make substantiative updates to the specifications of any of the quality measures in the IOTA Model. Additionally, we propose that the quality measures finalized for inclusion in the IOTA Model would remain in the quality measure set unless CMS, through future rulemaking, removed or replaced them.

We propose that CMS could remove or replace a quality measure based on one of the following factors:

- A quality measure does not align with current clinical guidelines or practice.
- Performance on a quality measure among IOTA participants is so high and unvarying that meaningful distinctions and improvement in performance can no longer be made (''topped out'' measure), as defined in 42 CFR 412.140(g)(3)(i)(A).

[243] Tong, A., Hanson, C.S., Chapman, J.R., Halleck, F., Budde, K., Josephson, M.A., & Craig, J.C. (2015). 'suspended in a paradox'-patient attitudes to wait-listing for Kidney Transplantation: Systematic review and thematic synthesis of qualitative studies. *Transplant International, 28*(7), 771–787. *https://doi.org/10.1111/tri.12575*.

[244] Ibid.

[245] *CMS ESRD Measures Manual for the 2023 Performance Period*. (2022). *https://www.cms.gov/files/document/esrd-measures-manual-v81.pdf*.

[246] Cukor, D., Donahue, S., Tummalapalli, S.L., Bohmart, A., & Silberzweig, J. (2022). Anxiety, comorbid depression, and dialysis symptom burden. *Clinical Journal of the American Society of Nephrology, 17*(8), 1216–1217. *https://doi.org/10.2215/cjn.01210122 https://doi.org/10.2215/cjn.01210122*.

[247] Jacobs, D.B., Schreiber, M., Seshamani, M., Tsai, D., Fowler, E., & Fleisher, L.A. (2023). Aligning quality measures across CMS—the Universal Foundation. *New England Journal of Medicine, 388*(9), 776–779. *https://doi.org/10.1056/nejmp2215539*.

[248] Szeifert, L., Bragg-Gresham, J.L., Thumma, J., Gillespie, B.W., Mucsi, I., Robinson, B.M., Pisoni, R.L., Disney, A., Combe, C., & Port, F.K. (2011). Psychosocial variables are associated with being wait-listed, but not with receiving a kidney transplant in the dialysis outcomes and Practice Patterns Study (dopps). *Nephrology Dialysis Transplantation, 27*(5), 2107–2113. *https://doi.org/10.1093/ndt/gfr568;* Chen, X., Chu, N.M., Basyal, P.S., Vihokrut, W., Crews, D., Brennan, D.C., Andrews, S.R., Vannorsdall, T.D., Segev, D.L., & McAdams-DeMarco, M.A. (2022). Depressive symptoms at kidney transplant evaluation and access to the kidney transplant waitlist. *Kidney International Reports, 7*(6), 1306–1317. *https://doi.org/10.1016/j.ekir.2022.03.008*.

- Performance or improvement on a quality measure does not result in better patient outcomes.
- The availability of a more broadly applicable quality measure (across settings or populations) or the availability of a quality measure that is more proximal in time to desired patient outcomes for the particular topic.
- The availability of a quality measure that is more strongly associated with desired patient outcomes for the particular topic.
- Collection or public reporting of a quality measure leads to negative unintended consequences other than patient harm.
- It is not feasible to implement the quality measure specifications.
- The costs associated with a quality measure outweigh the benefit of its continued use in the IOTA Model.

We propose that CMS would assess the benefits of removing or replacing a quality measure from the IOTA Model on a case-by-case basis. We propose that CMS would use the future rulemaking process to add, remove, suspend, or replace quality measures in the IOTA Model to allow for public comment, unless a quality measure raises specific safety concerns. We propose that if CMS determines that the continued requirement for IOTA participants to submit data on a quality measure raises specific patient safety concerns, CMS could elect to immediately remove the quality measure from the IOTA Model quality measure set. Finally, we propose that CMS would, upon removal of a quality measure, and in a form and manner determined by CMS, do the following:

- Provide notice to IOTA participants and the public at the time CMS removes the quality measure, along with a statement of the specific patient safety concerns that would be raised if IOTA participants continued to submit data on the quality measure.
- Provide notice of the removal in the **Federal Register**.

We seek comment on the requirement that IOTA participants report quality measure data to CMS. We additionally seek comment on our proposed process for adding, removing, or replacing quality measures in the IOTA Model.

(b) CollaboRATE Shared Decision-Making Score

The CollaboRATE Shared Decision-Making Score is a patient-reported measure of shared decision-making. The measure provides a performance score representing the percentage of adults 18 years of age and older who experience a high degree of shared decision making. The CollaboRATE Shared Decision-Making Score is based on three questions that assess the degree to which effort was made to inform the patient of his or her health issues, to listen to the patient's priorities, and the extent to which the patient's priorities were included in determining next steps. The measure is generic and applies to all clinical encounters, irrespective of the condition or the patient group. We propose that IOTA participants would be required to administer the CollaboRATE Shared Decision-Making Score to attributed patients once per PY, at minimum, and report quality measure data to CMS during survey and reporting windows, as defined in section III.C.5.e.(2).(a). of this proposed rule, that would be established by CMS.

We believe that incentivizing shared decision-making is critical to ensuring the model centers the patient experience and treatment choice to meet the IOTA desired goals of improving equity, increasing the number of kidney transplants, and reducing kidney non-utilization. Patients needing a kidney transplant often face many challenges when making healthcare decisions, as they must first decide between treatment options (such as dialysis versus transplantation, living donor versus deceased-donor transplantation) and where they wish to be evaluated for transplantation. Research findings demonstrate the importance and impact of shared decision-making throughout the entire transplant process for patients because of the types of complex decisions they must make, and the dynamic factors involved in each patient's decision.[249] Research studies have found that shared decision-making shifts the patient-physician relationship past traditional practices and contributes to better health outcomes, increased quality of life, increased patient knowledge and medication adherence, and lower healthcare expenditures.[250] Furthermore, research findings support that shared decision-making with the patient could reduce kidney non-utilization, improve equity,

[249] Jones, E.L., Shakespeare, K., McLaughlin, L., & Noyes, J. (2023). Understanding people's decisions when choosing or declining a kidney transplant: a qualitative evidence synthesis. BMJ Open, 13(8), e071348. *https://doi.org/10.1136/bmjopen-2022-071348;* Stephenson, M.D., & Bradshaw, W. (2018). Shared decision making in chronic kidney disease. Renal Society of Australasia Journal, 14(1), 26–32. *http://mutex.gmu.edu/login?url=https://www.proquest.com/scholarly-journals/shared-decision-making-chronic-kidney-disease/docview/2283078287/se-2;* Gordon, E.J., Butt, Z., Jensen, S.E., Lok-Ming Lehr, A., Franklin, J., Becker, Y., Sherman, L., Chon, W.J., Beauvais, N., Hanneman, J., Penrod, D., Ison, M.G., & Abecassis, M.M. (2013). Opportunities for Shared Decision Making in Kidney Transplantation. American Journal of Transplantation, 13(5), 1149–1158. *https://doi.org/10.1111/ajt.12195;* Salter, M.L., Babak Orandi, McAdams-DeMarco, M.A., Law, A., Meoni, L.A., Jaar, B.G., Sozio, S.M., Hong, W., Parekh, R.S., & Segev, D.L. (2014). Patient- and Provider-Reported Information about Transplantation and Subsequent Waitlisting. Journal of the American Society of Nephrology, 25(12), 2871–2877. *https://doi.org/10.1681/asn.2013121298;* Schold, J.D., Huml, A.M., Poggio, E.D., Reese, P.P., & Mohan, S. (2022). A tool for decision-making in kidney transplant candidates with poor prognosis to receive deceased donor transplantation in the United States. Kidney International. *https://doi.org/10.1016/j.kint.2022.05.025;* Schaffhausen, C.R., Bruin, M.J., McKinney, W.T., Snyder, J.J., Matas, A.J., Kasiske, B.L., & Israni, A.K. (2019). How patients choose kidney transplant centers: A qualitative study of patient experiences. 33(5), e13523–e13523. *https://doi.org/10.1111/ctr.13523;* Hart, A., Bruin, M., Chu, S., Matas, A., Partin, M.R., & Israni, A.K. (2019). Decision support needs of kidney transplant candidates regarding the deceased donor waiting list: A qualitative study and conceptual framework. Clinical Transplantation, 33(5), e13530. *https://doi.org/10.1111/ctr.13530;* S. Ali Husain, Brennan, C., Michelson, A., Tsapepas, D., Patzer, R.E., Schold, J.D., & Mohan, S. (2018). Patients prioritize waitlist over posttransplant outcomes when evaluating kidney transplant centers. 18(11), 2781–2790. *https://doi.org/10.1111/ajt.14985;* Patzer, R.E., McPherson, L., Basu, M., Mohan, S., Wolf, M., Chiles, M., Russell, A., Gander, J.C., Friedewald, J.J., Ladner, D., Larsen, C.P., Pearson, T., & Pastan, S. (2018). Effect of the iChoose Kidney decision aid in improving knowledge about treatment options among transplant candidates: A randomized controlled trial. American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 18(8), 1954–1965. *https://doi.org/10.1111/ajt.14693.*

[250] Stephenson, M.D., & Bradshaw, W. (2018). Shared decision making in chronic kidney disease. Renal Society of Australasia Journal, 14(1), 26–32. *http://mutex.gmu.edu/login?url=https://www.proquest.com/scholarly-journals/shared-decision-making-chronic-kidney-disease/docview/2283078287/se-2;* Gordon, E.J., Butt, Z., Jensen, S.E., Lok-Ming Lehr, A., Franklin, J., Becker, Y., Sherman, L., Chon, W.J., Beauvais, N., Hanneman, J., Penrod, D., Ison, M.G., & Abecassis, M.M. (2013). Opportunities for Shared Decision Making in Kidney Transplantation. American Journal of Transplantation, 13(5), 1149–1158. *https://doi.org/10.1111/ajt.12195;* Schold, J.D., Huml, A.M., Poggio, E.D., Reese, P.P., & Mohan, S. (2022). A tool for decision-making in kidney transplant candidates with poor prognosis to receive deceased donor transplantation in the United States. Kidney International. *https://doi.org/10.1016/j.kint.2022.05.025;* Schaffhausen, C.R., Bruin, M.J., McKinney, W.T., Snyder, J.J., Matas, A.J., Kasiske, B.L., & Israni, A.K. (2019). How patients choose kidney transplant centers: A qualitative study of patient experiences. 33(5), e13523–e13523. *https://doi.org/10.1111/ctr.13523;* Hart, A., Bruin, M., Chu, S., Matas, A., Partin, M.R., & Israni, A.K. (2019). Decision support needs of kidney transplant candidates regarding the deceased donor waiting list: A qualitative study and conceptual framework. Clinical Transplantation, 33(5), e13530. *https://doi.org/10.1111/ctr.13530;* Patzer, R.E., McPherson, L., Basu, M., Mohan, S., Wolf, M., Chiles, M., Russell, A., Gander, J.C., Friedewald, J.J., Ladner, D., Larsen, C.P., Pearson, T., & Pastan, S. (2018). Effect of the iChoose Kidney decision aid in improving knowledge about treatment options among transplant candidates: A randomized controlled trial. American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 18(8), 1954–1965. *https://doi.org/10.1111/ajt.14693.*

and increase the number of kidney transplants.[251]

By pairing the CollaboRATE Shared Decision-Making Score measure with the proposed achievement domain number of kidney transplants metric, as described in section III.C.5.c. of this proposed rule, and the proposed quality domain post-transplant outcomes metrics, as described in section III.C.5.e.(1). of this proposed rule, we aim to incentivize care delivery transformation and improvement activity across IOTA participants that would center attributed patients and their family and caregiver as a critical decision-maker in treatment choices that align with their preferences and values. This may include greater transparency on donor organ offers and reasons for non-acceptance, and increased education and support on the living donor process. We also believe that this would support attributed patients in receiving a kidney that may be at higher risk of non-use, but that may offer a survival and quality of life advantage over remaining on dialysis, dying while waitlisted, or being de-listed.[252]

We acknowledge that the instrument used for the CollaboRATE Shared Decision-Making Score is generic; however, we have not been able to identify alternative measures of shared decision-making that are specific to kidney transplant that have been endorsed by the CBE. Similarly, while there may be value in an instrument that measures shared decision-making regarding the types of kidney organ offers attributed patients are willing to accept, no such measure exists. We believe the CollaboRATE Shared Decision-Making Score would capture variation in the presence and quality of shared decision-making among IOTA participants and that the instrument need not be specific to kidney transplant to incentivize meaningful improvements in patient-centricity and the patient experience, equity, and reducing kidney non-use.

We seek comment on our proposal to include the CollaboRATE Shared Decision-Making Score as a quality measure for purposes of quality domain performance assessment.

(c) Colorectal Cancer Screening

The Colorectal Cancer Screening (COL) measure identifies the percentage of patients 50–75 years of age who had guideline concordant screening for colorectal cancer. Kidney transplant recipients are at higher risk for cancer than the general population, due in part to long-term immunosuppression.[253] Kidney transplant recipients have a higher incidence of colorectal cancer and advanced adenomas and may have worse prognoses than the general population, both of which support improved screening and prophylactic care for kidney transplant recipients.[254] [255] [256]

The COL measure is a Universal Foundation measure in the CMS Meaningful Measures 2.0 Wellness and Prevention Domain. By nature of its inclusion in the Universal Foundation measure set, the COL measure addresses a condition associated with significant morbidity and mortality and incentivizes action on high-value preventive care.[257] The COL measure is also aligned with the goals of the President's Cancer Moonshot to reduce the death rate from cancer by 50 percent over the next 25 years and improve the experience of people living with cancer and those who have survived it.[258]

We are proposing the COL measure for inclusion in our assessment of quality domain performance in the model because we believe it would provide a signal of the importance of ongoing post-transplant care and reduce variation in the screening and prophylactic care of kidney transplant recipients by transplant hospital. We propose that IOTA participants would be required to administer the COL measure yearly to all attributed IOTA transplant patients who are Medicare beneficiaries. The COL measure would work in concert with the proposed composite graft survival metric to increase the likelihood that attributed patients in the IOTA Model would receive comprehensive post-transplant care that would account not only for the attributed patient and graft survival, but also complications and comorbidities associated with receiving a kidney transplant.

We seek comment on our proposal to include the COL measure as a quality measure for purposes of quality domain performance assessment.

(d) 3-Item Care Transition Measure (CTM–3)

The 3-Item Care Transition Measure (CTM–3) is a hospital-level, patient-reported measure of readiness for self-care at time of discharge from an acute care hospital. The CTM–3 is based on data from a three-question instrument that assesses whether the patient and family's preferences were accounted for in the care plan; whether patients understood their role in self-management; and, whether appropriate medication education was provided. A higher score on the CTM–3 reflects a higher quality transition of care. We propose that IOTA participants would be required to administer the CTM–3 to attributed patients once per PY, at minimum, and report quality measure data to CMS during survey and reporting windows, as defined in section III.C.5.e.(2).(a). of this proposed rule, that would be established by CMS.

[251] Kucirka, L.M., Grams, M.E., Balhara, K.S., Jaar, B.G., & Segev, D.L. (2011). Disparities in Provision of Transplant Information Affect Access to Kidney Transplantation. American Journal of Transplantation, 12(2), 351–357. *https://doi.org/10.1111/j.1600-6143.2011.03865.x;* Patzer, R.E., Retzloff, S., Buford, J., Gander, J., Browne, T., Jones, H., Ellis, M., Canavan, K., Berlin, A., Mulloy, L., Gibney, E., Sauls, L., Muench, D., Reeves-Daniel, A., Zayas, C., DuBay, D., Mutell, R., & Pastan, S.O. (2021). Community Engagement to Improve Equity in Kidney Transplantation from the Ground Up: the Southeastern Kidney Transplant Coalition. Current Transplantation Reports, 8(4), 324–332. *https://doi.org/10.1007/s40472-021-00346-x;* Schold, J.D., Huml, A.M., Poggio, E.D., Reese, P.P., & Mohan, S. (2022). A tool for decision-making in kidney transplant candidates with poor prognosis to receive deceased donor transplantation in the United States. Kidney International. *https://doi.org/10.1016/j.kint.2022.05.025;* Patzer, R.E., McPherson, L., Basu, M., Mohan, S., Wolf, M., Chiles, M., Russell, A., Gander, J.C., Friedewald, J.J., Ladner, D., Larsen, C.P., Pearson, T., & Pastan, S. (2018). Effect of the iChoose Kidney decision aid in improving knowledge about treatment options among transplant candidates: A randomized controlled trial. American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 18(8), 1954–1965. *https://doi.org/10.1111/ajt.14693.*

[252] Massie, A.B., Luo, X., Chow, E.K.H., Alejo, J.L., Desai, N.M., & Segev, D.L. (2014). Survival benefit of primary deceased donor transplantation with high-KDPI kidneys. *American Journal of Transplantation, 14*(10), 2310–2316. *https://doi.org/10.1111/ajt.12830.*

[253] Rama, I., & Grinyó, J.M. (2010). Malignancy after renal transplantation: The role of immunosuppression. Nature Reviews Nephrology, 6(9), 511–519. *https://doi.org/10.1038/nrneph.2010.102.*

[254] Komaki, Y., Komaki, F., Micic, D., Ido, A., & Sakuraba, A. (2018). Risk of colorectal cancer in chronic kidney disease. Journal of Clinical Gastroenterology, 52(9), 796–804. *https://doi.org/10.1097/mcg.0000000000000880.*

[255] Privitera, F., Gioco, R., Civit, A.I., Corona, D., Cremona, S., Puzzo, L., Costa, S., Trama, G., Mauceri, F., Cardella, A., Sangiorgio, G., Nania, R., Veroux, P., & Veroux, M. (2021). Colorectal cancer after Kidney Transplantation: A screening colonoscopy case-control study. Biomedicines, 9(8), 937. *https://doi.org/10.3390/biomedicines9080937.*

[256] Farrugia, D., Mahboob, S., Cheshire, J., Begaj, I., Khosla, S., Ray, D., & Sharif, A. (2014). Malignancy-related mortality following kidney transplantation is common. Kidney International, 85(6), 1395–1403. *https://doi.org/10.1038/ki.2013.458.*

[257] Jacobs, D.B., Schreiber, M., Seshamani, M., Tsai, D., Fowler, E., & Fleisher, L.A. (2023). Aligning quality measures across CMS—the Universal Foundation. New England Journal of Medicine, 388(9), 776–779. *https://doi.org/10.1056/nejmp2215539.*

[258] Cancer Moonshot. (n.d.). The White House. *https://www.whitehouse.gov/cancermoonshot/.*

Transitions of care after kidney transplant are common and indicate elements of modifiable transplant hospital quality. One study found that 30-day hospital readmissions after an organ transplant were significantly associated with graft loss and death.[259] Poor understanding of and adherence to immunosuppressive drugs were identified as key elements associated with an increased risk for early hospital readmission.[260] Mitigating readmission risk may be of special importance given that IOTA participants may choose to increase their number of transplants by transplanting more kidneys that may have clinical value to patients. Simultaneously, there may also be increased healthcare utilization needs due to delayed graft function (DGF), which could require longer hospital stays, readmissions, and more complex care coordination.[261] We have also heard from interested parties about the need for patient-reported measures to contribute to the assessment of post-transplant outcomes.

The CTM–3 is a patient-reported measure and would measure transplant hospital performance on an aspect of care that we understand to be important to the patient experience, modifiable by transplant hospitals, and that may not otherwise improve based on the financial incentives in the model targeted towards 1- and 3-year outcomes, but not directly at perioperative transitions of care and readmission risk. The CTM–3 is a domain of the HCAHPS (CBE ID: 0166). We believe that IOTA participants would have some familiarity with the HCAHPS survey and that the hospital systems of which IOTA participants would be a part would have an infrastructure in place for the administration of HCAHPS that could be leveraged to support administration of the CTM–3.

We seek comment on our proposal to include the CTM–3 measure as a quality measure as a quality measure for purposes of quality domain performance assessment.

(e) Calculation of Points

We propose that the IOTA participant would receive up to 10 points for performance on our three proposed measures within the quality domain—the CollaboRATE Shared Decision-Making Score, COL, and CTM–3 measures. For purposes of quality measure set performance scoring, we propose that IOTA participants may receive up to 4 points for performance on the CollaboRATE Shared Decision-Making Score measure, up to 2 points on the COL measure, and up to 4 points on the CTM–3 measure. Lower weight in terms of scoring points was given to the COL measure because it is a claims-based measure that does not require reporting from IOTA participants. Because the CTM–3 and CollaboRATE are PRO–PMs we believe it is important to allot more points to them, to recognize the additional operational activities necessary for IOTA participants.

We propose to phase-in quality performance benchmarks for the three quality measures selected for the IOTA quality measure set, such that we would reward reporting for the first two years of the model performance period (''pay-for-reporting''), at minimum, before we reward performance against quality performance benchmarks for each measure (''pay-for-performance''). Thus, performance for each of these three quality measures would be measured against a ''response rate threshold'' applicable to our proposed ''pay-for-reporting'' method for PY 1–PY 2, while performance would be measured against quality performance benchmarks calculated by CMS applicable to our proposed ''pay-for-performance'' method for PY 3–PY 6. Table 8 illustrates our proposed pay-for-reporting and pay-for-performance timeline. We note that we anticipate establishing a quality performance benchmarks and minimum attainment levels for quality measures in future rule making.

TABLE 8: MEASURE PAYMENT TYPE BY PERFORMANCE YEAR

Measure	PY 1	PY 2	PY 3	PY 4	PY 5	PY 6
CollaboRATE Shared Decision-Making Score	Pay for Reporting (P4R)	P4R	Pay for Performance (P4P)	P4P	P4P	P4P
Colorectal Cancer Screening (COL)	P4R	P4R	P4P	P4P	P4P	P4P
CTM-3	P4R	P4R	P4P	P4P	P4P	P4P

We propose that CMS would determine and share with IOTA participants the response rate threshold by the first day of each PY in a form and manner chosen by CMS. This approach to assessing IOTA participant quality performance would serve four key purposes. First, it would promote measure implementation, uptake, and data collection by IOTA participants through a rewards-only scoring system. Second, it would build experience over the first two model PYs, giving IOTA participants more time to prepare and build capacity to meet performance benchmarks. Third, it would allow CMS to collect data needed to develop measure benchmarks. Finally, it would focus model incentives on care delivery transformation and improvement activity directly aimed at meeting quality performance goals, as to ensure the patient is centered in this approach. Ultimately, we considered the pay-for-reporting approach to be a reasonable approach. We also believe that some IOTA participants may be familiar with this as it is similar to the format within the KCC Model. We recognize that these measures already exist, but, because they are used in a much broader population, there are no benchmarks that are applicable for the model.

We propose to define the ''response rate threshold'' as the level of complete and accurate reporting for each quality measure, within the quality measure set of the quality domain, that the IOTA participant must meet to earn points on the quality domain during a performance year as described in § 512.428(c) and (e). For the CTM–3 and CollaboRATE measures, we propose that

[259] Covert, K.L., Fleming, J.N., Staino, C., Casale, J.P., Boyle, K.M., Pilch, N.A., Meadows, H.B., Mardis, C.R., McGillicuddy, J.W., Nadig, S., Bratton, C.F., Chavin, K.D., Baliga, P.K., & Taber, D.J. (2016). Predicting and preventing readmissions in Kidney Transplant Recipients. *Clinical Transplantation, 30*(7), 779–786. *https://doi.org/10.1111/ctr.12748.*

[260] Covert, K.L., Fleming, J.N., Staino, C., Casale, J.P., Boyle, K.M., Pilch, N.A., Meadows, H.B., Mardis, C.R., McGillicuddy, J.W., Nadig, S., Bratton, C.F., Chavin, K.D., Baliga, P.K., & Taber, D.J. (2016). Predicting and preventing readmissions in Kidney Transplant Recipients. *Clinical Transplantation, 30*(7), 779–786. *https://doi.org/10.1111/ctr.12748.*

[261] Jadlowiec, C.C., Frasco, P., Macdonough, E., Wagler, J., Das, D., Budhiraja, P., Mathur, A.K., Katariya, N., Reddy, K., Khamash, H., & Heilman, R. (2022). Association of DGF and early readmissions on outcomes following Kidney Transplantation. *Transplant International, 35. https://doi.org/10.3389/ti.2022.10849.*

points be awarded based on response rate thresholds, as illustrated in Table 9, such that IOTA participants with a response rate threshold of—

- 90–100 percent of attributed patients would receive 4 points;
- 50–89 percent of attributed patients would receive 2 points; or
- Under 50 percent of attributed patients would receive 0 points.

We propose for the COL measure that a completion rate of 50 percent or greater would result in the IOTA participant receiving two points, and a completion rate of less than 50 percent would result in the IOTA participant receiving zero points, as illustrated in Table 9.

TABLE 9 — IOTA MODEL QUALITY MEASURE SET SCORING

Measure	Performance Relative to Target	Lower Bound Condition	Upper Bound Condition	Points Earned
CollaboRATE/CTM-3	90% Response Rate	Equals 90%	Greater than 90%	4
CollaboRATE / CTM-3	50% Response Rate	Equals 50%	Less than 90%	2
CollaboRATE / CTM-3	50% Response Rate	N/A	Less than 50%	0
COL	50% Response Rate	Equals 50%	Greater than 50%	2
COL	50% Response Rate	N/A	Less than 50%	0

We recognize that the proposed response rate thresholds are high, but we want to make sure that we have enough data to set appropriate and meaningful benchmarks in PY 3 through PY 6. We considered setting a higher maximum measure completion rate; however, given that each IOTA participant may have different levels of engagement with kidney transplant waitlist patients, we believe a higher threshold may be difficult for IOTA participants to achieve. We also believe that a higher response rate would incentivize IOTA participants to collect the data. We considered the following variations to the response rate threshold for each of the proposed quality measure:

- Response rate threshold of 100 percent would receive 10 points, if not 100 percent 0 points would be awarded.
- Response rate threshold of 80–100 percent would receive 10 points, 50–79 percent would receive 5 points, and 49–0 percent would receive 0 points.
- 50–100 percent would receive 10 points; under 50 percent would receive 0 points.

We considered mirroring the point structure under which an IOTA participant would receive either all possible points, or, if data was not collected from all their attributed patients, none of the possible points. We believe this could incentivize IOTA participants to administer the surveys associated with the proposed quality measures, which would allow us to create meaningful benchmarks for future model years. However, because there would be some additional burden placed onto IOTA participants to administer the surveys associated with the proposed quality measures, we believe this point structure would be difficult for some and wanted to provide more attainable response rate thresholds. We also considered lowering the response rate thresholds for the same reasons mentioned earlier, but, because there are currently no benchmarks for these measures in this specific population, we believed the response rate threshold needed to be higher but still attainable.

We also considered achievement and improvement scoring for the proposed quality measures. However, because none of the measures included in the proposed quality measure set, as described in section III.C.5.e.(2). of this proposed rule, currently have benchmarks, we did not believe it was appropriate to propose achievement and improvement scoring for the proposed quality measures at this time.

We seek comment on our proposed calculation of points for the quality measure set, as well as the proposal to reward IOTA participant reporting for the first two PYs (''pay-for-reporting''), before rewarding IOTA participant performance against quality performance benchmarks. We seek comment on the proposed response rate thresholds and point allocations for measures included in the proposed quality measure set within the quality domain.

6. Payment

a. Purpose and Goals

We believe that risk-based payment arrangements in Innovation Center models drive healthcare innovation and transform the healthcare payment system by rewarding value over volume. Risk-based payment models hold participants financially accountable, as these payments are structured to incentivize value-based care that improves quality and reduces total cost of care for beneficiaries. Risk-based payment models may be upside-risk only, or have two-sided, upside and downside, risk. Under these risk-based arrangements, model participants may receive a payment from CMS if performance goals are met or exceeded, and, if the model features downside risk, may owe a payment to CMS for failing to meet performance goals.[262]

For the IOTA Model, we propose an alternative payment model (APM) structure that incorporates both upside and downside risk to existing Medicare fee-for-service (FFS) payments for kidney transplantations as described in section III.C.6.b. of this proposed rule.

The IOTA Model would test whether performance-based payments, including an upside risk payment and downside risk payment, to IOTA participants increases access to kidney transplants for attributed patients while preserving or enhancing quality of care and reducing program expenditures. As described in section III.C.5. of this proposed rule, IOTA participants would be assessed against proposed metrics to assess performance for each PY relative to specified targets, threshold, or benchmarks proposed and determined by CMS. The final performance score, not to exceed a maximum of 100 points, would determine if and how upside and downside risk payments are applied, as described in section III.C.6.c. of this proposed rule. We believe this upside and downside risk approach would be a strong incentive to promote performance improvement.

We seek comment on our proposed two-sided risk payment design to incentivize model performance goals.

b. Alternative Payment Design Overview

There are two payment components in the current Medicare FFS program for organ transplantation. Under the

[262] *https://www.cms.gov/priorities/innovation/key-concepts/risk-arrangements-health-care.*

Medicare Inpatient Prospective Payment System (IPPS), kidney transplant hospitals are paid a prospective payment system rate based on the MS–DRG for the organ transplant. Payment for organ acquisition costs as described at 42 CFR 413.402, which include costs associated with beneficiary and donor evaluation, is made on a reasonable cost basis. To remain active on the transplant waitlist, candidates must meet a variety of criteria, including annual screenings for cardiovascular diseases and cancers.

In the IOTA Model, CMS is proposing two-sided performance-based payments for ''Medicare kidney transplants,'' defined as kidney transplants furnished to attributed patients whose primary or secondary insurance is Medicare FFS, as identified in Medicare FFS claims with MS–DRGs 008, 019, 650, 651 and 652, and as illustrated in Table 10. This APM design aligns with the Health Care Payment Learning & Action Network (LAN) Category 3 APM framework in which model participants continue to be paid on the basis of Medicare FFS, but a retrospective annual attribution reconciliation and performance assessment after the end of each model PY is conducted to determine performance-based payments.[263]

The IOTA Model's performance-based payments are linked to existing Medicare Part A and Part B services for kidney transplants, and align with other Innovation Center models' payment structure, including the ETC Model where upward and downward adjustments are made to certain Medicare payments under the ESRD Prospective Payment System and Physician Fee Schedule depending on a n ETC Participant's performance at the aggregation group level under the model. The difference between ETC and the IOTA Model, for example, is how these retrospective adjustments would be paid or recouped by CMS. CMS is not proposing to adjust existing Medicare IPPS payments for kidney transplants furnished to Medicare beneficiaries. Instead, CMS is proposing to make performance-based payments to IOTA participants separate from claims-based payments.

TABLE 10: MS-DRGs PROPOSED FOR INCLUSION IN DEFINITION OF MEDICARE KIDNEY TRANSPLANTS

MS-DRG	Description
008	SIMULTANEOUS PANCREAS AND KIDNEY TRANSPLANT
019	SIMULTANEOUS PANCREAS AND KIDNEY TRANSPLANT WITH HEMODIALYSIS
650	KIDNEY TRANSPLANT WITH HEMODIALYSIS WITH MCC
651	KIDNEY TRANSPLANT WITH HEMODIALYSIS WITHOUT MCC
652	KIDNEY TRANSPLANT

We propose to base performance-based payments on increasing the number of transplants and other metrics of efficiency and quality because: (1) we believe it would be a strong proxy for total cost; (2) it directly aligns with the model's focused goal of increasing access and volume of kidney transplantations; (3) acknowledges kidney waitlist and transplant patients are high-cost and high-need, making performance based on total cost of care unfair for IOTA participants with lower volume and fewer capabilities and resources given increased opportunity for outliers; and (4) may safeguard against unintended consequences introduced by defining value based on cost for an attributed patient population already at high-risk, such as inappropriate cost shifting and widening access to care disparities. We theorize that increasing the number of, and access to, kidney transplants alone would result in better quality. As indicated in our estimates presented in section IV of this proposed rule, it would also result in savings to Medicare.

While we propose to assess model performance for each IOTA participant for all attributed patients regardless of payer type, as described in section III.C.6.c of this proposed rule, we propose model performance-based payments that would only be based on kidney transplants furnished to attributed patients with Medicare FFS as the primary or secondary insurance.

We considered also basing the model performance-based payments on kidney transplants furnished to attributed patients enrolled in Medicare Advantage (MA), as kidney transplants are a Medicare-covered service that MA plans must also cover. As these payments would be made to transplant hospitals, a potential waiver of section 1851(i)(2) of the Act, which provides that only the MA plan shall be entitled to payments for services furnished to the beneficiary, may have been necessary to apply the payments to attributed patients enrolled in MA. Because further consideration is needed for the implications of such a potential waiver, we are not proposing to apply model performance-based payments performed on attributed patients enrolled in MA.

We believe that the benefits of applying model performance-based payments to transplants furnished to attributed patients enrolled in MA would be recognizing the growth in MA enrollment relative to Medicare FFS enrollment, strengthening the model test through aligned payment incentives across payers, and protecting against unintended consequences of incentivizing inappropriate organ offer acceptance based on payer type. However, we are not proposing to base payments on attributed patients enrolled in MA, because of concerns about potentially waiving section 1851(i)(2) of the Act. This provision states that only the MA plan is entitled to payments for services provided to the beneficiary. Waiving this requirement would be unprecedented and the effects are unknown. We do recognize that the proposed incentives in the IOTA Model would have a larger effect if transplant hospitals were receiving performance-based payments based on their entire panel of attributed beneficiaries who receive transplants, and not just based on transplants for attributed beneficiaries with Medicare FFS as their primary or secondary insurance. To that end, the IOTA Model would encourage multi-payer alignment with the goal of aligning on goals, incentives, and quality. CMS intends to engage with the payer community, including MA,

[263] *https://hcp-lan.org/workproducts/apm-refresh-whitepaper-final.pdf.*

Medicaid, and commercial payers, to discuss opportunities and approaches for alignment.

We request comment and feedback, especially from MA plans, on our decision not to calculate model performance-based payments to transplants furnished to attributed patients enrolled in MA. We are especially interested in comments that address how the Innovation Center should generally approach the growing MA population with the design of its models, which have traditionally been focused on the fee-for-service Medicare population.

While kidney transplant hospitals are subject to value-based payment programs, some IOTA participants may have limited APM experience, resources, and capacity to meet model goals. We considered an upside-risk payment only framework that would still base model payments on kidney transplant utilization and other metrics of efficiency and quality. However, we believed that two-sided risk payments would be stronger incentives to achieve desired goals. We also recognized this in the model design by proposing a phased-in approach to two-sided risk, with upside-only applied to the first model PY. We also considered other APM frameworks that would link performance to quality, such as pay-for-reporting and pay-for-performance. We did not propose these frameworks, as they did not align with our goals of establishing two-sided risk accountability for IOTA participants. Recognizing the benefits of a rewards-focused approach, particularly as it relates to quality performance, we did incorporate a rewards-focused performance scoring structure designed as pay-for-reporting and pay-for-performance within the quality domain performance assessment.

Another alternative we considered was a flat positive adjustment to the Medicare FFS payment for a kidney transplant based on the number of completed kidney transplants that an IOTA participant performs. Increasing the amount paid for completed kidney transplants through a FFS adjustment is the simplest policy and aligns with a main focus of the IOTA Model; that is, increasing the number of kidney transplants. Additionally, adjusting the FFS payment would directly incentivize an increase in the number of kidney transplants performed by IOTA participants. Under this approach, eligible claims would be identified utilizing Medicare claims data with Medicare Severity Diagnosis Related Groups (MS–DRGs) 008 (simultaneous pancreas-kidney transplant) and 652 (kidney transplant); and claims with ICD–10 procedure codes 0TY00Z0 (transplantation of right kidney, allogeneic, open approach), 0TY00Z1 (transplantation of right kidney, syngeneic, open approach), 0TY00Z2 (transplantation of right kidney, zooplastic, open approach) 0TY10Z0 (transplantation of left kidney, allogeneic, open approach), 0TY10Z1 (transplantation of left kidney, syngeneic, open approach), and 0TY10Z2 (transplantation of left kidney, zooplastic, open approach).

We are not proposing a performance methodology based solely on adjusting the DRG payment for a kidney transplant, because this option would not encourage IOTA participants to focus on issues other than transplant volume, including equity, increased utilization of donor kidneys, quality of care, and patient outcomes, all of which are all important parts of the transplant process where we believe performance is variable and can be improved. We further believe that the claims-only approach would limit IOTA participant responsiveness to the model because IOTA participants that already have high kidney transplant volumes would be rewarded through increased reimbursements whether they improved year-over-year or not. Finally, we do not believe that this approach would provide any additional encouragement for IOTA participants to manage post-transplant care.

We also considered establishing a payment for transplant waitlist management to encourage additional investment in the transplant process, but decided to focus more on the outcomes described in section III.C.5 of this proposed rule. Additionally, given that IOTA participants are already reimbursed at cost for efforts to manage beneficiaries on the waitlist, we did not believe an explicit additional payment would be necessary in this area.

We seek feedback on our proposed alternative payment model design, data source to identify kidney transplants, and proposal to only apply model performance-based payments, both upside and downside, to Medicare kidney transplants. We also seek feedback on alternative approaches considered, including consideration of MA inclusion. We welcome input on how CMS may be able to work with multiple payers to ensure alignment with the IOTA Model.

c. Performance-Based Payment Method

We are proposing that the final performance score as described in section III.C.5. of this proposed rule would determine if and how an IOTA participant qualifies for an upside risk payment, falls in the neutral zone, or qualifies for a downside risk payment, proposed using a two-step process. First, we would determine if an IOTA participant's final performance score qualifies the IOTA participant for upside risk payments, downside risk payments, or the neutral zone, as described in section III.C.6.c.(1). of this proposed rule. Second, we would apply the proposed calculation formula for each of type of payment, as described in section III.C.6.c.(2). of this proposed rule. Ultimately, we are proposing a performance-based payment method that prioritizes the following principles:

- Significant weight should be given to performance in the achievement domain, representing up to 60 points relative to a 100 maximum performance score, in alignment with the primary goals of the model to increase number of kidney transplants.
- The magnitude of performance-based payments should be tied to relative number of kidney transplants, given significant differentials across kidney transplant hospitals nationally.
- The largest performance-based payments amount in total dollars should go to IOTA participants that perform the most transplants because they are removing the most people from dialysis and creating the largest quality improvement and cost savings for the Medicare Trust Fund.
- The payments need to be calibrated to provide an incentive to IOTA participants, but still ensure net savings to Medicare based on the analysis performed by OACT in section IV of this proposed rule.
- The mechanisms should recognize that CMS has not previously offered kidney transplant hospitals a value-based care payment model around transplantation and should provide a transition to any form of downside risk to allow for an opportunity to become familiar with the value-based care process.
- Limit operational complexity for both IOTA participants and CMS to avoid any potential for errors.

(1) Determine Final Performance Score Range Category

We propose to establish three final performance score range categories, as illustrated in Table 11, that dictate which type of performance-based payment would apply to an IOTA participant for a given PY.

We propose to define ''upside risk payment'' as a lump sum payment that CMS would make to an IOTA participant if the IOTA participant's final performance score for a PY falls

within the payment range specified in section III.C.6.c(2)(a) of this proposed rule. As proposed and indicated in Table 11, if in PY 1–6, an IOTA participant's final performance score is greater than or equal to 60 points, the IOTA participant would qualify for an upside risk payment.

We propose to define ''neutral zone'' as the final performance score range in which the IOTA participant would not owe a downside risk payment to CMS or receive an upside-risk payment from CMS if the IOTA participant's final performance score falls within the ranges specified in section III.C.6.c.(2).(c). of this proposed rule. In the first year of the model, we propose that the neutral zone would apply for final performance scores below 60. As such, only upside payments and the neutral zone would exist in PY 1. We are also proposing the neutral zone in PYs 2–6 would apply for final performance scores of 41–59 (inclusive). We believe that average performance should yield no upside or downside risk payment.

We propose to define ''downside risk payment'' as a lump sum payment the IOTA participant would be required to pay to CMS after a PY if the IOTA participant's final performance score falls within the ranges specified in section III.C.6.c.(2).(b). of this proposed rule. We propose that there will be no downside risk payment in the PY 1. We are proposing no downside risk payment in the first PY to allow IOTA participants time to implement changes to improve performance prior to facing downside risk. In PYs 2–6, we are proposing to introduce downside risk payments. We propose that an IOTA participant's final performance score of 40 or below in PYs 2–6, would result in a downside risk payment. We believe that below average performance should yield a downside risk payment.

The performance assessment scoring method, as described in section III.C.5. of this proposed rule, was designed such that IOTA participants with limited experience in APMs would still be likely to achieve a sufficient final performance score that would result in no downside risk payment. For example, it is expected that most IOTA participants would earn around 30 of 60 possible points in the achievement domain. We believe that average performance should be neither rewarded nor penalized. We also considered eliminating the neutral zone and only applying upside and downside performance payments, narrowing the neutral zone score range (that is, 44–55), or applying a wider-to-narrower phased-in approach over the model performance period. We believed these alternative options would be less flexible and more penalty-focused, with some IOTA participants more likely to be penalized due to varying degrees of capabilities and capacity that would limit their ability to achieve performance targets as they progress and evolve over the model performance period. Thus, we are opting to propose a neutral zone that would allow for more opportunities and incentives to achieve improvements over time without a large probability of downside risk.

TABLE 11. PROPOSED PERFORMANCE-BASED PAYMENTS BY FINAL PERFORMANCE SCORE

Final Performance Score	PY 1	PY 2 – 6
60-100	Upside Risk Payment	Upside Risk Payment
41-59	Neutral Zone	Neutral Zone
0 - 40	Neutral Zone	Downside Risk Payment

We seek feedback on the use of the final performance scores to determine the upside risk payment, the downside risk payment, and the neutral zone.

(2) Apply Payment Calculation Formula to Final Performance Score

We propose that after determining if an IOTA participant's final performance score qualifies the IOTA participant for an upside risk payment, downside risk payment, or the neutral zone, as described in section III.C.6.c.(1). of this proposed rule, we would apply a calculation formula unique to each PY to the final performance score, as specified in sections III.C.6.c.(2).(a). through (c). of this proposed rule.

(a) Upside Risk Payment

If, in PYs 1–6, an IOTA participant's final performance score is greater than or equal to 60 points, we propose that the IOTA participant would qualify for an upside risk payment. If an IOTA participant's final performance score would qualify them for the upside risk payment, we propose a methodology to calculate their upside risk payment using the formula in equation 2, where:

- $8,000 is a fixed, risk-based payment amount within the calculation formula, estimated to be about 33 percent of the average Medicare FFS kidney transplant MS–DRG cost. We aimed to create a strong financial incentive with significant earning opportunity for IOTA participants that meet or exceed model performance expectations. We believe this amount or proportion of the MS–DRG to be a large financial incentive to promote behavior changes while maintaining expectations of net savings to Medicare. We calibrated this based on projection of the incentive effects that would encourage the necessary support and infrastructure investment needed to achieve high performance and produce overall model savings and have the effects that we are looking for.
- The final performance score is the sum of points earned from the achievement domain, efficiency domain, and quality domain in a PY, as described in section III.C.5. of this proposed rule.
- Medicare kidney transplants is the number of Medicare kidney transplants furnished by the IOTA participant in a PY.

Equation 2: Proposed Upside Risk Payment Calculation Formula

$$\textit{Upside Risk Payment} = \$8{,}000 * ((\textit{Final Performance Score} - 60)/40) * \textit{Medicare Kidney Transplants}$$

We also considered calculating the maximum positive multiplier per Medicare kidney transplant claim based on the Kidney Transplant Bonus in the KCC Model. In 2019, the Kidney Transplant Bonus for entities participating in the KCC Model was set to $15,000. Adjusted for inflation, this is roughly $18,000, which would be the maximum allowable positive bonus payment per transplant. The Kidney Transplant Bonus was originally calculated based on the difference in spending between a beneficiary who went on to get a transplant and the average ESRD beneficiary cost.

However, we believe that the maximum positive adjustment may be too large in relation to current Medicare payments for kidney transplants for the model to yield net savings.

We also considered using a system similar to the Hospital VBP Program under which CMS withholds 2 percent of participating's hospitals Medicare payments and uses the sum of these reductions to fund value-based incentive payments to hospitals based on their performance under the program. However, we wished to have equal upside and downside multipliers across IOTA participants.

We also considered adjusting the maximum upside multiplier in PYs 2–6; however, we felt making that decision prior to the start of the model would be premature and wish to understand IOTA participant performance before making such a decision.

We seek comment on our proposed methodology to calculate the upside risk payment and alternatives considered.

(b) Downside Risk Payment

If an IOTA participant's final performance score is at or below 40 points in PYs 2—6, the IOTA participant would qualify for a downside risk payment. If an IOTA participant qualifies for a downside risk payment, we describe the methodology to calculate their downside risk payment risk using the formula in equation 3:

Equation 3: Proposed Downside Risk Payment Calculation Formula

$$\textit{Downside Risk Payment} = \$2{,}000 * ((40 - \textit{Final Performance Score})/40) * \textit{Medicare Kidney Transplants}$$

- $2,000 is a fixed, risk-based payment amount within the calculation formula, estimated to be about one-twelfth, or 8 percent, of the average Medicare FFS kidney transplant MS–DRG cost. We are proposing a lower downside-risk value relative to the upside-risk value proposed for the upside risk payments (about one-fourth lower) because we wanted to maintain a greater rewards approach, while still holding IOTA participants accountable for poor performance. We also believe that this approach is more flexible and accommodating to IOTA participants with no, or limited, APM experience, or that are more limited in terms of resources and capabilities.
- The final performance score is the sum of points earned from the achievement domain, efficiency domain, and quality domain, as described in section III.C.5. of this proposed rule.
- Medicare kidney transplants is the count of furnished Medicare kidney transplants during the PY.

We also considered applying the same fixed amount to both the upside and downside risk payment ($8,000 or $2,000 in both) or having the downside risk payment be 50 percent of the fixed amount of the upside risk payment ($4,000) but opted against it to maintain lower levels of risk given the fact that this model would be mandatory for eligible kidney hospitals. As discussed in section III.C.6.b of this proposed rule, we considered an upside-risk only payment framework, thus eliminating the application of downside-risk payments. Recognizing the potential for volatility in performance year-over-year, we also considered requiring IOTA participants to owe downside-risk payments to CMS if their final performance score was at or below 40 for more than one PY, starting from PY 1, potentially giving IOTA participants a similar phased-in, or, rather, ramp-up, opportunity to adjust and improve before downside-risk payments kick in. We considered this option to be unnecessary and operationally complex, particularly as it would function in a similar way as our proposed approach from a phasing-in standpoint. We also considered adjusting the $2,000 fixed, risk-based payment amount for PYs 2—6; however, we believe a fixed amount would provide greater transparency to IOTA participants on financial risk and model implementation experience would better inform if this approach would be necessary.

We seek comment on our proposed downside risk payment calculation formula, and alternatives considered.

(c) Neutral Zone

If, in PY 1, an IOTA participant's final performance score was below 60 points, or if, in PYs 2–6, an IOTA participant's final performance score was between 41 and 59 (inclusive), we propose that the final performance score, as described in section III.C.6.c.(1). of this proposed rule, would qualify the IOTA participant for the neutral zone, where no upside risk payment or downside risk payment would apply. As such, in a PY where an IOTA participant's final performance score falls in the neutral zone, no money would be paid to the IOTA participant by CMS, nor would money be owed by the IOTA participant to CMS.

We seek comment on our proposed neutral zone.

(3) Payments Operations and Timelines

After the end of each PY, CMS would assess each IOTA participant's performance in accordance with section III.C.5. of this proposed rule and calculate performance-based payments in accordance with the methodology specified in section III.C.6.c. of this proposed rule. We propose to define this process as ''preliminary performance assessment and payment calculations.''

We propose that CMS would conduct and calculate preliminary performance assessment and payment calculations at least 3 to 6 months after the end of each PY to allow for sufficient Medicare kidney transplant claims runout. We propose that CMS would notify IOTA participants of their preliminary model performance assessment, including the IOTA participant's score for each metric within the achievement domain, efficiency domain, and quality domain and the final performance score, and payment calculations with respect to any applicable upside risk payment or downside risk payment, at least 5 to 9 months after the end of each PY, allowing for a two-to-three month period for CMS to conduct calculations after the claims runout period. We propose that a 30-day notification period between preliminary and final calculations would apply, giving IOTA participants 30 days to review preliminary data and calculations and request targeted reviews, as described in section III.C.6.c.(4). of this proposed rule. This 30-day notification period would also be intended to provide IOTA participants with advance notice of forthcoming performance-based payments before upside risk payments or demand letters for downside risk payments would be issued by CMS. We also propose that CMS would notify IOTA participants of their model performance assessment and payment calculations in a form and manner determined by CMS, such as letters, email, or model dashboard. We propose that CMS would notify the IOTA participant of their final performance score and any associated upside risk payment or downside risk payment at least 30 days after notifying the IOTA participant of their preliminary model performance assessment and payment calculations.

We propose that after CMS notifies the IOTA participant of their final performance score and any associated upside risk payment and by a date determined by CMS, CMS would issue the upside risk payment to the tax identification number (TIN) on file for the IOTA participant in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS).

We propose that after CMS notifies the IOTA participant of their final

performance score and any associated downside risk payment and by a date determined by CMS, CMS would issue a demand letter to the TIN on file in PECOS for the IOTA participant for downside risk payments owed to CMS, with a payment due date of at least 60 days after the date on which the demand letter is issued. We propose that the demand letter would include details on model performance, the downside risk payment, and how payments would be made to CMS.

Rather than the proposed lump-sum payment and demand letter approach, we also considered making the upside risk payments and downside risk payments to IOTA participants in the form of Medicare FFS claim adjustments. The benefit of this approach would be that upside risk payments and downside risk payments, which are retrospective, would be applied prospectively and spread out over a 12-month period, so that a transplant hospital would not need to pay back to CMS a large sum of monies owed all at once. However, we believe that this approach would delay model payments and collection of monies owed to CMS. We also consider this approach to be disruptive to standard claims processing systems and operationally complex, with more opportunities for error and less flexibility to correct errors in a timely manner.

We seek comment on our proposed payment operations and timeline and alternative considered.

(4) Targeted Review

We believe that CMS calculation errors are possible, and therefore IOTA participants should be able to dispute the results of calculations.

Thus, upon receipt of CMS issued notifications of preliminary performance assessment and payment calculations, as described in section III.C.6.c.(3). of this proposed rule, we propose that IOTA participants may appeal via a ''targeted review process,'' defined as the process in which an IOTA participant could dispute performance assessment and payment calculations made, and issued, by CMS.

We propose that an IOTA participant would be able to request a targeted review for one or more calculations made and issued by CMS within the preliminary performance assessment and payment calculations. We propose that an IOTA participant would be able to request a targeted review for CMS consideration if—

- The IOTA participant believes an error occurred in calculations due to data quality or other issues; or
- The IOTA participant believes an error occurred in calculations due to misapplication of methodology.

We propose that an IOTA participant would be required to submit a targeted review request within 30 days, or another time period as specified by CMS, of receiving its preliminary performance assessment and payment calculations from CMS. We also propose the request would require supporting information from the IOTA participant, in a form and manner specified by CMS. The 30-day window to appeal generally aligns with the length of time we have finalized for submitting appeals in other CMS models, such as the ETC Model, as well as under the Hospital VBP Program, and we believe would allow ample time for IOTA participants to separately review CMS calculations.

We propose that the targeted review process would not provide IOTA participants the ability to dispute policy and methodology, as it would be limited to the dispute of calculations. Specifically, we propose that CMS will not consider targeted review requests regarding, without limitation, the following:

- The selection of the kidney transplant hospital to be an IOTA participant.
- The attribution of IOTA waitlist patients and the attribution of IOTA transplant patients to the IOTA participant, or to any other kidney transplant hospital selected for participation in the IOTA Model, or to any kidney transplant hospital not selected for participation in the IOTA Model.
- The methodology used for determining the achievement domain, efficiency domain, and quality domain.
- The methodology used for calculating and assigning points for each metric within the achievement domain, efficiency domain, and quality domain.
- The methodology used for calculating the payment amount per Medicare kidney transplant paid to an IOTA participant.

We propose that a targeted review request that includes one or more of the exclusions under § 512.434(c)(1) could still be reviewed by CMS, given that all remaining considerations of the request meet all other criteria for consideration by CMS.

Upon receipt of a targeted review request from an IOTA participant, we propose that CMS would conduct an initial assessment and final assessment of the targeted review. We believe that this proposal would be in line with other CMS models.

The CMS targeted review initial assessment would determine if the targeted review request met the targeted review requirements and contained sufficient information to substantiate the request. If the request was not compliant with the requirements or required additional information, CMS would follow up with IOTA participants to request additional information in a form and manner determined by CMS. Any additional information that CMS requests from an IOTA participant would be due to CMS within 30 days of CMS's request, also in a form and manner determined by CMS. An IOTA participant's non-responsiveness to the request for additional information from CMS could result in the closure of the targeted review request.

In a final assessment, CMS would determine whether it erred in a calculation, as disputed by the IOTA participant.

CMS's correction of an error may delay the date of payment of an IOTA participant's upside risk payments or downside risk payments.

Were a calculation error to be found as a result of an IOTA participant's targeted review request, we would notify the IOTA participant within 30 days of any findings in a form and manner determined by CMS and resolve and correct the error and discrepancy in the amount of the upside risk payment or downside risk payment in a time and manner as determined by CMS.

We propose that targeted review decisions made by CMS would be final, unless submitted by the IOTA participant or CMS for a CMS Administrator review. We are also proposing to include the reconsideration determination process as outlined in proposed § 512.190 in the IOTA Model.

We note that if an IOTA participant has regular Medicare FFS claims issues or decisions that it wishes to appeal (that is, issues during the model performance period with Medicare FFS that are unrelated to the model performance and payment calculations and payments), then the IOTA participant should continue to use the standard CMS procedures. Section 1869 of the Act provides for a process for Medicare beneficiaries, providers, and suppliers to appeal certain claims and decisions made by CMS.

We seek comment on our proposals regarding the process by which an IOTA participant could request a targeted review of CMS calculations.

(5) Extreme and Uncontrollable Circumstances

Events may occur outside the purview and control of the IOTA participant that may affect their performance in the model. In the event of extreme and uncontrollable circumstances, such as a public health emergency, we propose that CMS may reduce the downside risk payment, if any, prior to recoupment by an amount determined by multiplying the downside risk payment by the percentage of total months during the PY affected by an extreme and uncontrollable circumstance, by the percentage of attributed patients who reside in an area affected by the extreme and uncontrollable circumstance. We are proposing to address only the downside risk payment under this policy, as we wish to mitigate the harm to entities due to extreme and uncontrollable circumstances. We considered applying this policy to upside risk payments and final performance scores in the neutral zone, but we believe that IOTA participants that have been able to achieve model success do not need to be made whole by this policy.

We propose to apply determinations made under the Quality Payment Program with respect to whether an extreme and uncontrollable circumstance has occurred, and the affected areas, during the PY. We chose the Quality Payment Program to align across Innovation Center models and CMS policy. We propose that CMS has the sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred and the percentage of attributed patients residing in affected areas for the IOTA participant.

We request comment on our extreme and uncontrollable circumstances policy and whether the determinations by the Quality Payment Program that an extreme and uncontrollable circumstance has occurred should apply to IOTA participants.

7. Data Sharing

a. General

We expect that IOTA participants would work toward independently identifying and producing their own data, through electronic health records, health information exchanges, or other means that they believe are necessary to best evaluate the health needs of their patients, improve health outcomes, and produce efficiencies in the provision and use of services.

To assist IOTA participants in this process, we propose to provide IOTA participants with certain beneficiary-identifiable data for their Medicare beneficiaries who are attributed patients, upon request. We anticipate that IOTA participants would use this data to better assess transplant readiness and post-transplant outcomes. We also propose to provide certain aggregate data that has been de-identified in accordance with the HIPAA Privacy Rule, 45 CFR 164.514(b), as discussed below, for the purposes of helping IOTA participants understand their progress towards the model's performance metrics.

Specifically, subject to the limitations discussed in this proposed rule, and in accordance with applicable law, including the HIPAA Privacy Rule, we propose that CMS may offer an IOTA participant an opportunity to request certain Medicare beneficiary-identifiable data and reports as discussed in section III.C.7.b of this proposed rule. We propose that CMS would share beneficiary identifiable data with IOTA participants on the condition that the IOTA participants, their IOTA collaborators, and other individuals or entities performing functions or services related to the IOTA participant's activities observe all relevant statutory and regulatory provisions regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information, and comply with the terms of the data sharing agreement described in this section of the proposed rule.

We propose that the beneficiary-identifiable claims data described in section III.C.7.b of this proposed rule would omit individually identifiable data for Medicare beneficiaries who have opted out of data sharing with the IOTA participant, as described in section III.C.7.c of this proposed rule. We also note that, for the beneficiary-identifiable claims data, we would exclude information that is subject to the regulations governing the confidentiality of substance use disorder patient records (42 CFR part 2) from the data shared with an IOTA participant.

b. Beneficiary-Identifiable Data

(1) Legal Authority To Share Beneficiary-Identifiable Data

We believe that an IOTA participant may need access to certain Medicare beneficiary-identifiable data for the purposes of evaluating its performance, conducting quality assessment and improvement activities, conducting population-based activities relating to improving health or reducing health care costs, or conducting other health care operations listed in the first or second paragraph of the definition of ''health care operations'' under the HIPAA Privacy Rule, 45 CFR 164.501.

We propose that, subject to providing the beneficiary with the opportunity to decline data sharing as described in section III.C.10.a of this proposed rule, and subject to having a valid data sharing agreement in place, an IOTA participant may request from CMS certain beneficiary identifiable claims for attributed patients who are Medicare beneficiaries.

We recognize there are sensitivities surrounding the disclosure of individually identifiable (beneficiary-specific) health information, and several laws place constraints on the sharing of individually identifiable health information. For example, section 1106 of the Act generally bars the disclosure of information collected under the Act without consent unless a law (statute or regulation) permits the disclosure. Here, the HIPAA Privacy Rule would allow for the proposed disclosure of individually identifiable health information by CMS.

Under the HIPAA Privacy Rule, covered entities (defined in 45 CFR 160.103 as health care plans, health care providers that submit certain transactions electronically, and health care clearinghouses) are barred from using or disclosing individually identifiable health information (called ''protected health information'' or PHI) in a manner that is not explicitly permitted or required under the HIPAA Privacy Rule, without the individual's authorization. The Medicare FFS program, a ''health plan'' function of the Department, is subject to the HIPAA Privacy Rule limitations on the disclosure of PHI without an individual's authorization. IOTA participants are also covered entities, provided they are health care providers as defined by 45 CFR 160.103 and they or their agents electronically engage in one or more HIPAA standard transactions, such as for claims, eligibility or enrollment transactions. In light of these relationships, we believe that the proposed disclosure of the beneficiary-identifiable data under the IOTA model would be permitted by the HIPAA Privacy Rule under the provisions that permit disclosures of PHI for ''health care operations'' purposes. Under those provisions, a covered entity is permitted to disclose PHI to another covered entity for the recipient's health care operations purposes if both covered entities have or had a relationship with the subject of the PHI to be disclosed, the PHI pertains to that relationship, and the recipient will use the PHI for a ''health care

operations'' function that falls within the first two paragraphs of the definition of ''health care operations'' in the HIPAA Privacy Rule (45 CFR 164.506(c)(4)).

The first paragraph of the definition of health care operations includes ''conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines,'' and ''population-based activities relating to improving health or reducing health costs, protocol development, case management and care coordination.'' The second paragraph of the definition of health care operations includes ''evaluating practitioner and provider performance'' (45 CFR 164.501).

Under our proposal, IOTA participants would be using the data on their patients to evaluate the performance of the IOTA participant and other providers and suppliers that furnished services to the patient, conduct quality assessment and improvement activities, and conduct population-based activities relating to improved health for their patients. When done by or on behalf of a covered entity, these are covered functions and activities that would qualify as ''health care operations'' under the first and second paragraphs of the definition of health care operations at 45 CFR 164.501. Hence, as previously discussed, we believe that this provision is extensive enough to cover the uses we would expect an IOTA participant to make of the beneficiary-identifiable data and would be permissible under the HIPAA Privacy Rule. Moreover, our proposed disclosures would be made only to HIPAA covered entities that have (or had) a relationship with the subject of the information, the information we would disclose would pertain to such relationship, and those disclosures would be for purposes listed in the first two paragraphs of the definition of ''health care operations.'' Finally, the proposed disclosures would be limited to beneficiary-identifiable data that we believe would meet HIPAA requirements in 45 CFR 164.502(b) to limit PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.

The Privacy Act of 1974 also places limits on agency data disclosures. The Privacy Act applies when Federal agencies maintain systems of records by which information about an individual is retrieved by use of one of the individual's personal identifiers (names, Social Security numbers, or any other codes or identifiers that are assigned to the individual). The Privacy Act generally prohibits disclosure of information from a system of records to any third party without the prior written consent of the individual to whom the records apply (5 U.S.C. 552a(b)).

''Routine uses'' are an exception to this general principle. A routine use is a disclosure outside of the agency that is compatible with the purpose for which the data was collected. Routine uses are established by means of a publication in the **Federal Register** about the applicable system of records describing to whom the disclosure will be made and the purpose for the disclosure. We believe that the proposed data disclosures are consistent with the purposes for which the data discussed in this rule was collected, and, thus, would not run afoul of the Privacy Act, provided we ensure that an appropriate Privacy Act system of records ''routine use'' is in place prior to making any disclosures. The systems of records from which CMS would share data are the Medicare Integrated Data Repository (IDR) and the Health Resources and Services Administration (HRSA) Organ Procurement and Transplantation Network (OPTN)/Scientific Registry of Transplant Recipients (SRTR) Data System. We believe that the proposed data disclosures are consistent with the purposes for which the data discussed in the proposed rule were collected and may be disclosed in accordance with the routine uses applicable to those records.

We propose that CMS would share the following beneficiary-identifiable lists and data with IOTA participants that have submitted a formal request for the data. Under our proposal, the request must be submitted on an annual basis in a manner and form and by a date specified by CMS. The request also would need to identify the data being requested and include an attestation that (A) the IOTA participant is requesting this beneficiary-identifiable data as a HIPAA covered entity or as a business associate, as those terms are defined at 45 CFR 160.103, to the IOTA participant's providers and suppliers who are HIPAA covered entities; and (B) the IOTA participant's request reflects the minimum data necessary for the IOTA participant to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501. In addition, IOTA participants who request this data must have a valid and signed data sharing agreement in place, as described in more detail later in this section. We propose that we would make available beneficiary-identifiable data as described in section III.C.8.b. of this proposed rule for IOTA participants to request for purposes of conducting health care operations that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of their attributed patients who are Medicare beneficiaries. We believe that access to beneficiary-identifiable claims data would improve care coordination between IOTA participants and other health care providers. Patients can spend months in between their visits to the kidney transplant hospital at which they are listed, and the post-transplant period is critical to transplant success. We believe that improved care coordination would improve outcomes and keep patients engaged in their care.

We also propose that IOTA participants limit the request for beneficiary-identifiable claims data to Medicare beneficiaries whose name appears on the quarterly attribution list who have been notified in compliance with section III.C.10.a. of this proposed rule, and who did not decline having their claims data shared with the IOTA participant, as proposed in section III.C.7.d. of this proposed rule. Finally, we propose that CMS would share beneficiary identifiable data with an IOTA participant on the condition that the IOTA participant, its IOTA collaborators, and other individuals or entities performing functions or services related to the IOTA participant's activities, observe all relevant statutory and regulatory provisions regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information and comply with the terms of the data sharing agreement described in section III.C.7.f. of this proposed rule.

(2) Quarterly Attribution Lists

We propose that this data would include, for the relevant PY, a beneficiary attribution report, shared quarterly, that would include a list of attributed patients and patients who have been de-attributed from the IOTA participant. We propose that the report would include at least the following information for each attributed patient: the attribution year the attributed patient became attributed to the IOTA participant; the effective date of the attributed patient's attribution to the IOTA participant; the effective date of the patient's de-attribution from the IOTA participant and the reason for such removal (if applicable); and the attributed patient's data sharing preferences made pursuant to section III.C.7.d. of this proposed rule. We propose that CMS may include additional information at its discretion in any of the quarterly attribution reports as data becomes available. Such

data may include information from the SRTR or OPTN on waitlist status or transplant status.

We request comment on whether such additional information would be beneficial to IOTA participants or whether this information is best accessed by the IOTA participant through other means.

(3) Beneficiary-Identifiable Claims Data

We propose to offer certain beneficiary-identifiable claims data to IOTA participants no later than 1 month after the start of each PY, in a form and manner specified by CMS. We propose that IOTA participants may retrieve this data at any point during the relevant PY and that it would include, at a minimum—

- Three years of historical Parts A, B, and D claims data files for attributed patients who are Medicare beneficiaries for 36 months immediately preceding the effective date of the Medicare beneficiary's attribution to the IOTA participant;
- Monthly Parts A, B, and D claims data files specified for attributed patients who are Medicare beneficiaries; and
- Monthly Parts A, B, and D claims data files for Medicare beneficiaries who have been de-attributed from the IOTA participant for claims with a date of service prior to the date the Medicare beneficiary was removed from attribution to the IOTA participant.

We propose that CMS would omit from the beneficiary-identifiable claims data any substance use disorder patient records subject to 42 U.S.C. 290dd–2 and the implementing regulations at 42 CFR part 2.

We believe these data elements would consist of the minimum data element necessary for IOTA participants to effectively manage the care of Medicare beneficiaries who are attributed patients. Specifically, this data would allow IOTA participants to coordinate care across the continuum as Medicare beneficiaries who are attributed patients transition from IOTA waitlist patients to IOTA transplant patients.

c. Minimum Necessary Data

We propose IOTA participants must limit their beneficiary-identifiable data requests to the minimum necessary to accomplish a permitted use of the data. We propose the minimum necessary Parts A and B data elements may include, but are not limited to, the following data elements:

- Beneficiary Identification (ID).
- Procedure code.
- Gender.
- Diagnosis code.
- Claim ID.
- The from and through dates of service.
- The provider or supplier ID.
- The claim payment type.
- Date of birth and death, if applicable.
- Tax Identification Number (TIN).
- National Provider Identification (NPI).

We propose the minimum necessary Part D data elements may include, but are not limited to, the following data elements:

- Beneficiary ID.
- Prescriber ID.
- Drug service date.
- Drug product service ID.
- Quantity dispensed.
- Days supplied.
- Brand name.
- Generic name.
- Drug strength.
- TIN.
- NPI.
- Indication if on formulary.
- Gross drug cost.

We request comment and feedback on the minimum beneficiary-identifiable claims data necessary for IOTA participants to request for purposes of conducting permissible health care operations purposes under this model.

d. Medicare Beneficiary Opportunity To Decline Data Sharing

As described in section III.C.10.a. of this proposed rule, we propose that Medicare beneficiaries must receive notification about the IOTA model. We also propose that Medicare beneficiaries must be given the opportunity to decline claims data sharing, and instructions on how to inform CMS directly of their preference.

We propose that Medicare beneficiaries would be notified about the opportunity to decline claims data sharing through the notifications proposed in section III.C.10.a. of this proposed rule. We propose that these notifications must state that the IOTA participant may have requested beneficiary identifiable claims data about the Medicare beneficiary for purposes of its care coordination and quality improvement work and/or population-based activities relating to improving health or reducing health care costs, and inform the Medicare beneficiary how to decline having his or her claims information shared with the IOTA participant in the form and manner specified by CMS. We propose that Medicare beneficiary requests to decline claims data sharing would remain in effect unless and until a beneficiary subsequently contacts CMS to amend that request to permit claims data sharing with IOTA participants.

We propose that Medicare beneficiaries may not decline to have the aggregate, de-identified data proposed in section III.C.7.f. of this proposed rule shared with IOTA participants. We also propose that Medicare beneficiaries may not decline to have the: initial attribution lists, quarterly attribution lists, and annual attribution reconciliation list as proposed in section III.C.4.b.(2)., b.(3). and b.(4). of this proposed rule shared with IOTA participants. We note that, in accordance with 42 U.S.C. 290dd–2 and its implementing regulations at 42 CFR part 2, CMS does not share beneficiary identifiable claims data relating to the diagnosis and treatment of substance use disorders under this model.

We note that the proposed opt out provisions discussed in this section would relate only to the proposed sharing of beneficiary-identifiable data between the Medicare program and the IOTA participant under the IOTA Model, and are in no way intended to impede existing or future data sharing under other authorities or models.

We request comment and feedback on our proposed policies to enable Medicare beneficiaries to decline data sharing.

e. Data Sharing Agreement

(1) General

As noted in section III.C.7.a. of this proposed rule, we propose that, prior to receiving any beneficiary-identifiable data, IOTA participants would be required to first complete, sign, and submit—and thereby agree to the terms of—a data sharing agreement with CMS. We propose that under the data sharing agreement, the IOTA participant would be required to comply with the limitations on use and disclosure that are imposed by HIPAA, the applicable data sharing agreement, and the statutory and regulatory requirements of the IOTA Model. We also propose that the data sharing agreement would include certain protections and limitations on the IOTA participant's use and further disclosure of the beneficiary-identifiable data and would be provided in a form and manner specified by CMS. Additionally, we propose that an IOTA Participant that wishes to retrieve the beneficiary-identifiable data would be required to complete, sign, and submit to CMS a signed data sharing agreement at least annually. We believe that it is important for the IOTA Participant to complete and submit a signed data sharing agreement at least annually so that CMS has up-to-date information that the IOTA participant wishes to retrieve the

beneficiary-identifiable data and information on the designated data custodian(s). As described in greater detail later in this section, we propose that a designated data custodian would be the individual(s) that an IOTA participant would identify as responsible for ensuring compliance with all privacy and security requirements and for notifying CMS of any incidents relating to unauthorized disclosures of beneficiary-identifiable data.

CMS believes it is important for the IOTA participant to first complete and submit a signed data sharing agreement before it retrieves any beneficiary-identifiable data to help protect the privacy and security of any beneficiary-identifiable data shared by CMS with the IOTA participant. As noted previously in this section of the proposed rule, there are important sensitivities surrounding the sharing of this type of individually identifiable health information, and CMS must ensure to the best of its ability that any beneficiary-identifiable data that it shares with IOTA participants would be further protected in an appropriate fashion.

We solicit public comment on our proposal to require that the IOTA participant agree to comply with all applicable laws and terms of the data sharing agreement as a condition of retrieving beneficiary-identifiable data, and on our proposal that the IOTA participant would need to submit the signed data sharing agreement at least annually if the IOTA participant wishes to retrieve the beneficiary-identifiable data.

(2) Content of the Data Sharing Agreement

We propose that CMS would share the following beneficiary-identifiable data with IOTA participants that have requested the data and have a valid data sharing agreement in place, as described in more detail later in this section. We propose that an IOTA participant that wishes to receive beneficiary-identifiable data for its attributed patients who are Medicare beneficiaries must also agree to certain terms, namely: (1) to comply with the requirements for use and disclosure of this beneficiary-identifiable data that are imposed on covered entities by the HIPAA regulations at 45 CFR part 160 and part 164, subparts A and E, and the requirements of the proposed IOTA model; (2) to comply with additional privacy, security, breach notification, and data retention requirements specified by CMS in the data sharing agreement; (3) to contractually bind each downstream participant of the beneficiary-identifiable data that is a business associate of the IOTA participant, including all IOTA collaborators, to the same terms and conditions with the IOTA participant is itself bound in its data sharing agreement with CMS as a condition of the business associate's receipt of the beneficiary-identifiable data retrieved by the IOTA participant under the IOTA model; and (4) that if the IOTA participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the data sharing agreement, CMS may: (A) deem the IOTA participant ineligible to retrieve the beneficiary-identifiable data under paragraph (b) of this section for any amount of time; (B) terminate the IOTA participant's participation in the IOTA model under § 512.466; and (C) subject the IOTA participant to additional sanctions and penalties available under the law.

CMS believes that these proposed terms for sharing beneficiary-identifiable data with IOTA participants are appropriate and important, as CMS must ensure to the best of its ability that any beneficiary-identifiable data that it shares with IOTA participants would be further protected by the IOTA participant, and any business associates of the IOTA participant, in an appropriate fashion.

CMS seeks public comment on the additional privacy, security, breach notification, and other requirements that we would include in the data sharing agreement. CMS has these types of agreements in place as part of the governing documents of other models tested under section 1115A of the Act and in the Medicare Shared Savings Program. In these agreements, CMS typically requires the identification of data custodian(s) and imposes certain requirements related to administrative, physical, and technical safeguards relating to data storage and transmission; limitations on further use and disclosure of the data; procedures for responding to data incidents and breaches; and data destruction and retention. These provisions would be imposed in addition to any restrictions required by law, such as those provided in the HIPAA privacy, security, and breach notification regulations. These data sharing agreement provisions would not prohibit the IOTA participant from making any disclosures of the data otherwise required by law.

CMS also seeks public comment on what specific disclosures of the beneficiary identifiable data might be appropriate to permit or prohibit under the data sharing agreement. For example, CMS is considering prohibiting, in the data sharing agreement, any further disclosure, not otherwise required by law, of the beneficiary-identifiable data to anyone who is not a HIPAA covered entity or business associate, as defined in 45 CFR 160.103, or to an individual practitioner in a treatment relationship with the attributed patient who is a Medicare beneficiary, or that practitioner's business associates. Such a prohibition would be similar to that imposed by CMS in other models tested under section 1115A of the Act in which CMS shares certain beneficiary-identifiable data with model participants for their health care operations.

CMS is considering these possibilities because there exist important legal and policy limitations on the sharing of the beneficiary-identifiable data and CMS must carefully consider the ways in which and reasons for which we would provide access to this data for purposes of the IOTA model. CMS believes that some IOTA participants may require the assistance of business associates, such as contractors, to perform data analytics or other functions using this beneficiary-identifiable data to support the IOTA participant's review of their care management and coordination, quality improvement activities, or clinical treatment of IOTA beneficiaries. CMS also believes that this beneficiary-identifiable data may be helpful for any HIPAA covered entities who are in a treatment relationship with the IOTA beneficiary.

We seek public comment on how an IOTA participant might need to, and want to, disclose the beneficiary-identifiable data to other individuals and entities to accomplish the goals of the IOTA model, in accordance with applicable law.

Under our proposal, the data sharing agreement would include other provisions, including requirements regarding data security, retention, destruction, and breach notification. For example, we are considering including, in the data sharing agreement, a requirement that the IOTA participant designate one or more data custodians who would be responsible for ensuring compliance with the privacy, security and breach notification requirements for the data set forth in the data sharing agreement; various security requirements like those found in participation agreements for other models tested under section 1115A of the Act, but no less restrictive than those provided in the relevant Privacy

Act system of records notices; how and when beneficiary-identifiable data could be retained by the IOTA participant or its downstream recipients of the beneficiary-identifiable data; procedures for notifying CMS of any breach or other incident relating to the unauthorized disclosure of beneficiary-identifiable data; and provisions relating to destruction of the data. These are only examples and are not the only terms CMS would potentially include in the data sharing agreement.

We solicit public comment on this proposal to impose certain requirements in the IOTA data sharing agreement related to privacy, security, data retention, breach notification, and data destruction.

f. Aggregate Data

We propose that CMS would share certain aggregate performance data with IOTA participants in a form and manner to be specified by CMS. This aggregate data would be de-identified in accordance with HIPAA requirements at 45 CFR 164.514(b) and would include, when available, transplant target data.

We propose that, for the relevant PY, CMS would provide aggregate data to the IOTA participant detailing the IOTA participant's performance against the transplant target, as described in section III.C.5.c.(2). of this proposed rule.

We seek comment and feedback on our proposal to share aggregate data with IOTA participants.

8. Other Requirements

a. Transparency Requirements

(1) Publication of Patient Selection Criteria for Kidney Transplant Evaluations

Transplant hospitals are currently required to use written patient selection criteria in determining a patient's suitability for placement on the waitlist or a patient's suitability for transplantation per the CoP (see 42 CFR part 482.90). If the transplant hospital performs living donor transplants, the transplant hospital must use written donor selection criteria to determine the suitability of candidates for donation.[264] The patient selection criteria must ensure fair and non-discriminatory distribution of organs, and the program must document in the patient's medical record the patient selection criteria used.[265] Prior to placement on the transplant hospital's waitlist, a prospective transplant candidate must receive a psychosocial evaluation, if possible.[266] Before a transplant hospital places a transplant candidate on its waitlist, the candidate's medical record must contain documentation that the candidate's blood type has been determined.[267] In addition, when a patient is placed on a hospital's waitlist or is selected to receive a transplant, the transplant hospital must document in the patient's medical record the patient selection criteria used.[268] Currently, the transplant hospital must also provide a copy of its patient selection criteria to a transplant patient, or a dialysis facility, as requested by the patient or a dialysis facility. For living donor selection, the transplant hospital's living donor selection criteria must be consistent with the general principles of medical ethics.[269] [270] Transplant hospitals must also ensure that a prospective living donor receives a medical and psychosocial evaluation, document in the living donor's medical records the living donor's suitability for donation, and document that the living donor has given informed consent.[271]

Available data and studies demonstrate that disparities exist for patients in underserved communities who seek or are referred for, or are evaluated for a transplant and who eventually are placed on a transplant waitlist and receive an organ transplant.[272] For instance, the data has shown that White patients are more likely than Black patients to be referred for organ transplant, while Black patients are less likely than White patients to be referred for transplant evaluation.[273] Racial disparities also exist in transplant wait listing, even after correcting for SDOH.[274] In addition, there are sex and gender disparities in access to the kidney transplant waitlist, with men more likely to have access compared to women.[275] Finally, a recent article in the Journal of the American Medical Association considers how transplant programs factor patient financial resources into waitlist decisions.[276] The authors' review of several studies suggest that socioeconomically deprived patients were proportionally less likely to be selected for placement on a waitlist for an organ transplant. They suggest, based on the strong and consistent associations between race and poverty, that ''withholding transplants from those with inadequate financial resources equates to an example of structural racism in the health care system.'' We refer readers to the numerous additional studies regarding disparities in organ transplantation and organ donation that are cited throughout this proposed rule.

To improve transparency for those looking to gain access to a transplant waitlist in the transplant program evaluation processes, we propose to require IOTA participants to publicly post, on a website, their patient selection criteria for evaluating patients for addition to their kidney transplant waitlist by the end of PY 1. We propose to finalize this requirement only if it is not redundant with other HHS guidance. We also considered requiring that IOTA participants update their selection criteria at a certain frequency to ensure that attributed patients have the most up to date information. However, we are unsure what cadence of update would be most appropriate.

We solicit public comments on this proposal and on how often the selection criteria should be updated by the IOTA participant.

(2) Transparency Into Kidney Transplant Organ Offers

Those active on a kidney transplant waitlist may receive organ offers at any time. However, there is currently no

[264] *https://www.ecfr.gov/current/title-42/section-482.90.*

[265] Ibid.

[266] Ibid.

[267] Ibid.

[268] Ibid.

[269] OPTN. (n.d.). *OPTN Policies—Living Donation, Chapter 14. https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.*

[270] AMA Council on Ethical and Judicial Affairs. (2019). AMA Code of Medical Ethics' Opinions on Organ Transplantation. *AMA Journal of Ethics, 14*(3), 204–214. *https://doi.org/10.1001/virtualmentor.2012.14.3.coet1-1203.*

[271] *https://www.ecfr.gov/current/title-42/section-482.90.*

[272] Park, C., Jones, M.-M., Kaplan, S., Koller, F.L., Wilder, J.M., Boulware, L.E., & McElroy, L.M. (2022). A scoping review of inequities in access to organ transplant in the United States. International Journal for Equity in Health, 21(1). *https://doi.org/10.1186/s12939-021-01616-x.*

[273] Epstein, A.M., Ayanian, J.Z., Keogh, J.H., Noonan, S.J., Armistead, N., Cleary, P.D., Weissman, J.S., David-Kasdan, J.A., Carlson, D., Fuller, J., Marsh, D., & Conti, R.M. (2000). Racial Disparities in Access to Renal Transplantation—Clinically Appropriate or Due to Underuse or Overuse? *New England Journal of Medicine, 343*(21), 1537–1544. *https://doi.org/10.1056/nejm200011233432106.*

[274] Ng, Y.-H., Pankratz, V.S., Leyva, Y., Ford, C.G., Pleis, J.R., Kendall, K., Croswell, E., Dew, M.A., Shapiro, R., Switzer, G.E., Unruh, M.L., & Myaskovsky, L. (2019). Does Racial Disparity in Kidney Transplant Wait-listing Persist After Accounting for Social Determinants of Health? *Transplantation,* 1. *https://doi.org/10.1097/tp.0000000000003002.*

[275] Ahern, Patrick et al. Sex Disparity in Deceased-Donor Kidney Transplant Access by Cause of Kidney Disease. 2021. *Clinical Journal of the American Society of Nephrology.* 16 (2) 241–250, *https://cjasn.asnjournals.org/content/16/2/241.*

[276] Wadhwani, S.I., Lai, J.C., & Gottlieb, L.M. (2022). Medical Need, Financial Resources, and Transplant Accessibility. *JAMA, 327*(15), 1445. *https://doi.org/10.1001/jama.2022.5283.*

requirement for providers to discuss organ offers with their patients. A provider may decline an organ offer for any number of reasons; however, declining without disclosing the rationale with the patient may miss an important opportunity for shared decision-making.

We propose to add requirements to increase transparency for IOTA waitlist patients who are Medicare beneficiaries regarding the volume of organ offers received on their behalf while on the waitlist. Specifically, we propose that for each month an organ is offered for an IOTA waitlist patient who is a Medicare beneficiary, an IOTA participant must inform the Medicare beneficiary, on a monthly basis, of the number of times an organ is declined on the Medicare beneficiary's behalf and the reason(s) for the decline. We are not proposing to prescribe the method of this notification, but would require that the medical record reflect that the patient received this information and the method by which it was delivered (for example, mail, email, medical appointment, internet portal/dashboard, etc.). We propose that this information must be shared with the IOTA waitlist patient who is a Medicare beneficiary, and should be shared, where deemed appropriate, with their nephrologist or nephrology professional, to provide the opportunity for questions and clarification of information.

Organ offer filters are a tool that transplant programs can use to bypass organ offers they would not accept. Offer filters were tested during two pilot programs and released nationally in January 2022.[277] We propose that IOTA participants would be required to review transplant acceptance criteria and organ offer filters with their IOTA waitlist patients who are Medicare beneficiaries at least once every 6 months that the Medicare beneficiary is on their waitlist. We propose that this review may be done on an individual basis in a patient visit, via phone, email, or mail. We believe that sharing this information with the patient would offer an opportunity for shared decision-making between the patient and IOTA participants and may increase the patient's quality of care. We propose that Medicare beneficiaries would be able to decline this review with the IOTA participant, as some may not wish to have this information. We anticipate that the Medicare beneficiary may decline this review during their next provider visit or over the phone.

We solicit public comment on whether an alternative frequency of sharing of organ offers with the Medicare beneficiary is more appropriate. We also solicit comment on whether there is a more suitable timeframe and frequency for addressing acceptance criteria with attributed patients. Per 42 CFR 482.94(c), and 482.102(a) and (c), kidney transplant hospitals currently review these criteria with patients upon patient request. Our goal is to provide a balance of transparency and patient engagement in this process without being overly prescriptive or burdensome. We also recognize that there are beneficiaries on the waitlist who may not be eligible to receive an organ offer for multiple years, so we seek feedback on whether this requirement should be limited to beneficiaries who have received or are likely to receive an organ offer in the next year.

(3) Publication of IOTA Participant Results

In the Specialty Care Models final rule (85 FR 61114), CMS established certain general provisions in 42 CFR part 512 subpart A that apply to all Innovation Center models. One such general provision pertains to rights in data. Specifically, in the Specialty Care Models final rule, we stated that to enable CMS to evaluate the Innovation Center models 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 part 512.140(a).

Consistent with these provisions, we propose to publish results from all PYs of the IOTA Model. Specifically, for each PY, we intend to post performance across the achievement domain, efficiency domain, and quality domain for each IOTA participant. We would also identify each IOTA participant for the PY. The results would be published on the IOTA Model website. Given that we have proposed that the IOTA Model would include a process for IOTA participants to request a targeted review of the calculation of performance score which is calculated based on the various rates we intend to publish, CMS anticipates that it would publish these rates only after they have been finalized and CMS has resolved any targeted review requests timely received from IOTA participants under section II.E. of this proposed rule. We believe that the release of this information would inform the public about the cost and quality of care and about IOTA participants' performance in the IOTA Model. This would supplement, not replace, the annual evaluation reports that CMS is required to conduct and release to the public under section 1115A(b)(4) of the Act.

We considered requiring IOTA participants to publish their performance results on their own websites as well to increase transparency; however, we did not want to place additional reporting burden on IOTA participants, particularly because we propose that CMS would publish the performance results, which should be adequate.

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.

b. Health Equity Data Reporting

(1) Demographic Data Reporting

As previously discussed in section III.B. of this proposed rule, and throughout this proposed rule, disparities exist throughout the transplant process. These circumstances highlight the importance of data collection and analysis that includes race, ethnicity, language, disability, sexual orientation, gender identity, and sex characteristics or other demographics by health care facilities. Such data are necessary for integration of health equity in quality programs, because the data permits stratification by patient subpopulation.[278] [279] Stratified data can produce meaningful measures that can be used to expose

[277] *Optimizing Usage of Kidney Offer Filters—OPTN.* (n.d.). Optn.*transplant.hrsa.gov.* Retrieved March 11, 2023, from *https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/optimizing-usage-of-kidney-offer-filters/.*

[278] IOM (Institute of Medicine). 2009. *Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement* (p.287). The National Academies Press *https://www.ahrq.gov/sites/default/files/publications/files/iomracereport.pdf.*

[279] Sivashanker, K., & Gandhi, T.K. (2020). Advancing Safety and Equity Together. *New England Journal of Medicine, 382*(4), 301–303. *https://doi.org/10.1056/nejmp1911700.*

health disparities, develop focused interventions to reduce them, and monitor performance to ensure interventions to improve care do not have unintended consequences for certain patients.[280] Furthermore, quality programs are carried out with well-known and widely used standardized procedures, including but not limited to, root cause analysis, plan-do-study-act (PDSA) cycles, health care failure mode effects analysis, and fish bone diagrams. These are common approaches in the health care industry to uncover the causes of problems, show the potential causes of a specific event, test a change that is being implemented, prevent failure by correcting a process proactively, and identify possible causes of a problem and sort ideas into useful categories, respectively.[281] [282] [283] [284] Adding a health equity prompt to these standardized procedures integrates a health equity lens within the quality structure and cues considerations of the patient subpopulations who receive care and services from a transplant hospital.[285]

To align with other Innovation Center efforts, we considered proposing that, beginning with the first PY and each PY thereafter, each IOTA participant would be required to collect and report to CMS demographic and SDOH data pursuant to 42 CFR part 403.1110(b) for the purposes of monitoring and evaluating the model. We considered proposing that, in conducting the collection required under this section, the IOTA participant would make a reasonable effort to collect demographic and social determinants of health data from all attributed patients but, in the case the IOTA participant attributed patient elects not to provide such data to the IOTA participant, the IOTA participant would indicate such election by the attributed patient in its report to CMS.

We decided not to propose the collection of demographic data as this data is already collected by OPOs and the SRTR, thereby making such a requirement for purposes of this model potentially duplicative and unnecessarily burdensome. We wish to minimize reporting burden on IOTA participants where possible to ensure sufficient time and effort is spent adjusting to the requirements of a mandatory model.

We solicit public comment on the decision not to propose the collection of this data and potential applications.

(2) Health Related Social Needs (HRSN) Data Reporting

The Innovation Center is charged with testing innovations that improve quality and reduce the cost of health care. There is strong evidence that non-clinical drivers of health are the largest contributor to health outcomes and are associated with increased health care utilization and costs.[286] [287] These individual-level, adverse social conditions that negatively impact a person's health or healthcare are referred to as ''health-related social needs'' or HRSNs.[288] CMS aims to expand the collection, reporting, and analysis of standardized HRSNs data in its efforts to drive quality improvement, reduce health disparities, and better understand and address the unmet social needs of patients. Standardizing HRSN Screening and Referral as a practice can inform larger, community-wide efforts to ensure the availability of and access to community services that are responsive to the needs of Medicare beneficiaries.

HRSN screening is becoming increasingly common nationally, but implementation is not uniform across geography or health care setting. A literature review of national surveys measuring prevalence of social screening found that almost half of State Medicaid agencies have established managed care contracting requirements for HRSN screening in Medicaid.[289] It also found that health care payers and/or delivery organizations reported a screening prevalence of 55–77 percent, with ''the highest estimate reported among American Hospital Association member hospitals.'' [290] Despite screening proliferation and generally positive views toward screening among both patients and health care providers, implementation of screening and referral policies for beneficiaries of CMS programs with similar health—and even demographic—profiles may be inconsistent, potentially exacerbating disparities in the comprehensiveness and quality of care.

One of the goals stated in the Innovation Center Strategy Refresh for advancing system transformation is to require all new models to collect and report demographic and SDOH data. Thus, in addition to the proposed health equity requirements in section III.C.8.b. of this proposed rule, we considered proposing a requirement that IOTA participants conduct HRSN screening for at least four core areas—food security, housing, transportation, and utilities. We recognize these areas as some of the most common barriers to kidney transplantation and the most pertinent for the IOTA participant patient population. However, given the need for a psychosocial evaluation prior to addition to the waitlist, we understand that such a requirement may be redundant given current clinical practices, we have refrained from making such a proposal.

We seek comment on whether we should include a requirement for IOTA participants to conduct HRSN screening and report HRSN data in a form and manner specified by CMS each PY for their attributed patients. We are seeking input on following the questions in this section, and comment on any aspect of the psychosocial evaluation of waitlisted patients and how this compares to HRSN screenings for the four domains—food security, housing, transportation, and utilities. Even if CMS were to adopt an HRSN screening and reporting requirement in the final rule, CMS might consider delaying the implementation of such a requirement.

[280] Weinick, R.M., & Hasnain-Wynia, R. (2011). Quality Improvement Efforts Under Health Reform: How To Ensure That They Help Reduce Disparities—Not Increase Them. *Health Affairs, 30*(10), 1837–1843. *https://doi.org/10.1377/hlthaff.2011.0617.*

[281] American Society for Quality. (2019). *What is root cause analysis (RCA)?* Asq.org. *https://asq.org/quality-resources/root-cause-analysis.*

[282] Agency for Healthcare Research and Quality. (2020). *Plan-Do-Study-Act (PDSA) directions and examples. www.ahrq.gov. https://www.ahrq.gov/health-literacy/improve/precautions/tool2b.html.*

[283] *Failure Modes and Effects Analysis (FMEA) Tool | IHI—Institute for Healthcare Improvement.* (2017). *www.ihi.org. https://www.ihi.org/resources/Pages/Tools/FailureModesandEffectsAnalysisTool.aspx.*

[284] Kane, R. (2014). *How to Use the Fishbone Tool for Root Cause Analysis. https://www.cms.gov/medicare/provider-enrollment-and-certification/qapi/downloads/fishbonerevised.pdf.*

[285] Sivashanker, K., & Gandhi, T.K. (2020). Advancing Safety and Equity Together. *New England Journal of Medicine, 382*(4), 301–303. *https://doi.org/10.1056/nejmp1911700.*

[286] Booske, B.C., Athens, J.K., Kindig, D.A., Park, H., & Remington, P.L. (2010). *County Health Rankings* (Working Paper). *https://www.countyhealthrankings.org/sites/default/files/differentPerspectivesForAssigningWeightsToDeterminantsOfHealth.pdf.*

[287] *ROI Calculator for Partnerships to Address the Social Determinants of Health Review of Evidence for Health-Related Social Needs Interventions.* (2019). *https://www.commonwealthfund.org/sites/default/files/2019-07/COMBINED-ROI-EVIDENCE-REVIEW-7-1-19.pdf.*

[288] 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 NPRM (citing A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool) 87 FR 38554 (June 28, 2022).

[289] De Marchis, E., Brown, E., Aceves, B., Loomba, V., Molina, M., Cartier, Y., Wing, H., Ma, L., & Gottlieb. (n.d.). *State of the Science of Screening in Healthcare Settings siren State of the Science on Social Screening in Healthcare Settings Summer 2022. https://sirenetwork.ucsf.edu/sites/default/files/2022-06/final%20SCREEN%20State-of-Science-Report%5B55%5D.pdf.*

[290] Ibid.

- When evaluating a patient for potential addition to the kidney transplant waitlist, what questions are asked as part of the psychosocial evaluation?
- How might a psychosocial evaluation compare to an HRSN screening? What HRSNs are identified as part of a psychosocial evaluation?
- What data is collected from the psychosocial evaluation on HRSNs?
- If HRSNs are identified as part of the evaluation process, what, if any, steps are taken to assist the patient in addressing these needs and improving their transplant readiness?
- If HRSNs are identified of a patient already on the transplant waitlist, how might this affect their status on the transplant waitlist? Could a patient be removed from the transplant waitlist if HRSNs are identified that may impact transplant readiness?
- What, if any, follow-up is conducted with waitlist patients that have identified HRSNs?
- Are there any concerns with HRSN screening and data collection requirements?

c. Health Equity Plans

To further align with other Innovation Center models and promote health equity across the transplant process, we propose that, for PY 2 through PY 6, each IOTA participant must submit to CMS, in a form and manner and by the date(s) specified by CMS, a health equity plan. Given that this would be a mandatory model, we propose that the health equity plan be voluntary in the first PY of the model to allow IOTA participants time to adjust to model requirements. We propose that the health equity plan must:

- Identify target health disparities. We propose to define ''target health disparities'' as health disparities experienced by one or more communities within the IOTA participant's population of attributed patients that the IOTA participant would aim to reduce.
- Identify the data sources used to inform the identification of target health disparities.
- Describe the health equity plan intervention. We propose to define ''health equity plan intervention'' as the initiative(s) the IOTA participant would create and implement to reduce target health disparities.
- Include a resource gap analysis. We propose to define ''resource gap analysis'' as the resources needed to implement the health equity plan interventions and identifies any gaps in the IOTA participant's current resources and the additional resources that would be needed.
- Include a health equity project plan. We propose to define ''health equity project plan'' as the timeline for the IOTA participant to implement the IOTA participant's the health equity plan.
- Identify health equity plan performance measure(s). We propose to define ''health equity performance plan measure(s)'' as one or more quantitative metrics that the IOTA participant would use to measure the reductions in target health disparities arising from the health equity plan interventions.
- Identify health equity goals and describes how the IOTA participant would use the health equity goals to monitor and evaluate progress in reducing targeted health disparities. We propose to define ''health equity goals'' as targeted outcomes relative to the health equity plan performance measures for the first PY and all subsequent PYs.

We propose that once an IOTA participant submits their health equity plan to CMS, CMS will use reasonable efforts to approve or reject the health equity plan within 60 business days. We propose that if CMS approves the IOTA participant's health equity plan, the IOTA participant must engage in activities related to the execution of the IOTA participant's health equity plan, including implementing health equity plan interventions and monitoring and evaluating progress in reducing target health disparities. Discrimination on the basis of race, ethnicity, national origin, religion, or gender in activities related to the execution of the IOTA participant's health equity plan would be prohibited.

Should CMS determine that the IOTA participant's health equity plan does not satisfy the proposed requirements and is inconsistent with the applicable CMS Health Equity Plan guidance, does not provide sufficient evidence or documentation to demonstrate that the health equity plan is likely to accomplish the IOTA participant's intended health equity goals, or is likely to result in program integrity concerns or negatively impact beneficiaries' access to quality care, we propose that CMS may reject the health equity plan or require amendment of the health equity plan at any time, including after its initial submission and approval.

We propose that if CMS rejects the IOTA participant's health equity plan, in whole or in part, the IOTA participant must not, and must require its IOTA collaborators to not, conduct health equity activities identified in the health equity plan that have been rejected by CMS.

We propose that in PY 3, and each subsequent PY, in a form and manner and by the date(s) specified by CMS, each IOTA participant would be required to submit to CMS an update on its progress in implementing its health equity plan. This update would be required to include all of the following:

- Updated outcomes data for the health equity plan performance measure(s).
- Updates to the resource gap analysis.
- Updates to the health equity project plan.

We propose that if an IOTA participant fails to meet the requirements of the heath equity plan described in this section of the proposed rule, the IOTA participant would be subject to remedial action as specified in section III.C.16. of this proposed rule. Such remedial actions could include: corrective action such as recoupment of any upside risk payments; or termination from the model.

We solicit feedback on these proposals. We also solicit comment on the potential impact of creation of a health equity plan, whether such plans should be voluntary, and whether health equity plans should only be a requirement in later PYs of the IOTA Model.

9. Overlap With Other Innovation Center Models, CMS Programs, and Federal Initiatives

a. Other Innovation Center Models and CMS Programs

We propose that IOTA participants would be allowed to simultaneously participate in IOTA and other CMS programs and models. The IOTA Model would overlap with several other CMS programs and models and Departmental regulatory efforts, and we seek comment on our proposals to account for overlap.

KCC Model—The KCC Model is a voluntary Innovation Center model for nephrologists, dialysis facilities, transplant providers, and other providers and suppliers that are focused on beneficiaries with CKD and beneficiaries with ESRD. The KCC Model performance period began on January 1, 2022, and is scheduled to end December 31, 2026. As such, the KCC Model would run concurrently for 2 years with the IOTA Model, which would have a proposed start date of January 1, 2025. The KCC Model includes a payment incentive called the Kidney Transplant Bonus (KTB). KCC participants are eligible for up to $15,000 for every aligned beneficiary

with CKD or ESRD who receives a kidney transplant, whether from a living or deceased donor, provided the transplant remains successful. Kidney Contracting Entities (KCEs) participating in the KCC Model are also required to include a transplant provider, defined as a transplant program that provides kidney transplants, a transplant hospital that provides kidney transplants, a transplant surgeon who provides kidney transplants, a transplant nephrologist, a transplant nephrology practice, an OPO, or another Medicare-enrolled provider or supplier that provides kidney transplant related covered services to Medicare beneficiaries.

Though transplant hospitals are one of the types of health care provider eligible to serve as a transplant provider, CMS has found relatively low participation by transplant hospitals in the KCC Model. Across the 100 KCEs participating in the model in 2023, there were only 10 kidney transplant hospitals participating in the model and serving as the transplant provider for the relevant KCE. In discussions with participants and with kidney transplant hospitals, CMS heard a few reasons for this relatively low rate of participation. CMS heard that it was difficult administratively for kidney transplant hospitals to participate as they are part of corporate entities that may have a larger organizational focus on broader shared savings efforts, rather than just for the kidney population.

We propose that any providers or suppliers participating in the KCC Model that meet the proposed IOTA participant eligibility requirements would still be required to participate in the IOTA Model. We believe that granting an exemption to the IOTA Model for these providers or suppliers could disrupt the patterns of care being tested in the KCC Model. We also believe that a prohibition on dual participation could prevent enough KCEs from having a transplant provider and meeting model requirements, which could undermine participation in the KCC model.

We considered proposing that any transplant hospitals participating in the IOTA Model would not be able to participate in the KCC Model and be able to receive any portion of a Kidney Transplant Bonus payment. However, we did not believe this was necessary given that there are currently only 10 transplant hospitals participating in the KCC Model, meaning that dual participation should not substantially affect the evaluation of either model. We also considered proposing that any kidney transplant for an aligned beneficiary that results in a Kidney Transplant Bonus being paid out in the KCC Model would not be counted for calculating an upside risk payment or downside risk payment in the IOTA Model. We decided not to propose this policy because of potential disruption to the KCC Model, which would be in its fourth performance year when the proposed IOTA Model would likely begin in 2025. Additionally, the Kidney Transplant Bonus payment in the KCC Model serves multiple functions within that model, as it also incentivizes post-transplant care for up to 3 years post-transplant.

We believe that it is important to test both the IOTA Model and the KCC Model, to test the effectiveness of payment incentives for kidney transplants at different points of the care coordination process. The IOTA Model would test the effect of upside and downside risk payments for kidney transplant hospitals, while the KCC Model tests how nephrologists and other providers and suppliers can support transplantation in the overall care coordination process. Upside risk payment and downside risk payment from the IOTA Model would not be counted as expenditures for purposes of the KCC Model, as they would not be adjustments to claims for individual beneficiaries, but would be paid out in a lump sum based on aggregate performance directly tied to individual beneficiary level claims. Additionally, we do not want to potentially hurt KCC participants that have beneficiaries who could benefit from the KCC participant's potential high performance in the IOTA Model.

Both the KCC Model and the IOTA Model would include explicit incentives for participants when aligned beneficiaries receive kidney transplants; and a transplant hospital participating in both models would be eligible to receive a portion of a Kidney Transplant Bonus from a KCE under the KCC Model and an upside risk payment or downside risk payment under the IOTA Model. Kidney transplants represent the most desired and cost-effective treatment for most beneficiaries with ESRD, but providers and suppliers may currently have insufficient financial incentives to assist beneficiaries through the transplant process because dialysis generally results in higher reimbursement over a more extended period of time than a transplant. As a result, CMS believes it would be appropriate to allow a transplant hospital to receive both an upside risk payment or downside risk payment from the IOTA Model and portion of a Kidney Transplant Bonus from the KCC Model and the IOTA Model simultaneously to assess their effects on the transplant rate.

ETC Model—The ETC Model is a mandatory Innovation Center model that includes as participants certain clinicians who manage dialysis patients (referred to as Managing Clinicians) and ESRD facilities and provides incentives for increasing rates of home dialysis, transplant waitlisting, and living donor transplantation. The ETC Model began on January 1, 2021, and the model performance period is scheduled to end December 31, 2025, and it would have one year of overlap with the proposed model performance period of the IOTA Model beginning January 1, 2025. The ETC Model includes an upward or downward payment adjustment called the Performance Payment Adjustment (PPA) that is calculated in part based on the rates of transplant waitlisting and living donor transplants for the population of beneficiaries aligned to a participating Managing Clinician or ESRD facility.

We believe that the goals of the ETC Model and the goals of the proposed IOTA Model are aligned. As CMS described in the 2020 rule finalizing the ETC Model (85 FR 61114), ''[t]he ETC Model [is] a mandatory payment model focused on encouraging greater use of home dialysis and kidney transplants.'' We believe that the IOTA Model would then test a corresponding incentive on the transplant hospital side to further assist beneficiaries in moving through the transplant process to get a transplant. CMS believes it is appropriate to test both models as the ETC Model does not include direct incentives for transplant hospitals and we believe that transplant hospitals play a very important role in the transplant process.

We note for the ETC Model, participants are selected based on their location in a Selected Geographic Area, which are randomly selected Hospital Referral Regions (HRR), stratified by census region, representing approximately one third of the country, as well as HRRs predominately comprised of ZIP codes in Maryland. This is a different randomization strategy than is being proposed for the IOTA Model. It is our intent to look at the effects of each model and its randomization strategy on the transplant rate as part of our model evaluation, which is discussed in section III.C.12 of this proposed rule.

Additionally, we note that the ETC Model includes the ETC Learning Collaborative as part of its model test. This is further discussed in section III.C.13. of this proposed rule, where we seek feedback about the experience of

kidney transplant hospitals, OPOs, ETC Participants, and other interested parties engaged in the ETC Learning Collaborative, as we consider how to best promote shared learning in the IOTA Model.

Other Medicare Alternative Payment Models (APMs)—For the Medicare Shared Savings Program (the Shared Savings Program) and the ACO Realizing Equity, Access, and Community Health (ACO REACH) Model, which focus on total cost of care, payment adjustments made under the IOTA Model would not be counted as program expenditures. The Medicare Shared Savings Program regulations address payments under a model, demonstration, or other time-limited program when defining program expenditures. Specifically, when calculating Shared Savings and Shared Losses for an ACO in the Shared Savings Program, CMS considers only ''individually beneficiary identifiable final payments made under a demonstration, pilot, or time limited program'' to be a part of the ACO's Medicare Parts A and B fee-for-service expenditures (see, for example, 42 CFR 425.605(a)(5)(ii)). Similarly, in the ACO REACH Model, an ACO's performance year expenditure is defined to include the total payment that has been made by Medicare fee-for-service for services furnished to REACH Beneficiaries (see ACO REACH Model First Amended and Restated Participation Agreement (Dec. 1, 2023)). Payments under the IOTA Model are not directly tied to any specific beneficiary. Instead, they are made on a lump sum basis based on aggregate performance across transplant patients seen by the center during the performance year. IOTA Model payments, therefore, would not be considered by the Shared Savings Program as an amount included in Part A or B fee-for-service expenditures or by the ACO REACH Model as an amount included in payment for REACH Beneficiaries' Medicare fee-for-service services.

Hospital VBP Program—CMS adjusts payments to hospitals under the Inpatient Prospective Payment System (IPPS) based on their performance under the Hospital VBP Program. However, the Hospital VBP Program does not currently include any measures related to transplant services. In addition, transplant services are only offered by a subset of hospitals. Given the different focuses between the Hospital VBP Program and the IOTA Model, we are not proposing any changes to the Hospital VBP Program and believe it is appropriate to test the IOTA Model alongside the existing Hospital VBP Program.

b. Overlap With Departmental Regulatory Efforts

December 2020 OPO Conditions for Coverage—In December 2020, CMS issued a final rule entitled ''Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Final Rule'' (85 FR 77898). The final rule revised the OPO CfCs and was intended to increase donation rates and organ transplantation rates by replacing the previous outcome measures. In general, the new outcome measures improve on the prior measures by using objective, transparent, and reliable data, rather than OPO self-reported data, to establish the donor potential in the OPO's DSA. The rule also permits CMS to begin decertifying underperforming OPOs beginning in 2026.

We believe that the proposed IOTA Model supports the policies set out in that final rule. We note that we have received feedback from OPOs and other interested parties that OPOs are required to procure more organs, while there is not a corresponding incentive on the transplant hospital side to transplant more organs into beneficiaries. We also note that the number of discarded organs has risen from 21 percent to 25 percent from 2018 to 2022.[291] Though there have been other changes during that time, including the updated organ allocation system and the effects of the COVID–19 pandemic, this rise in discarded organs is highly concerning, and we believe that the IOTA Model can help to mitigate this troubling rise by giving transplant hospitals an incentive to accept more offers that they may not have accepted without that incentive.

In September 2019, CMS finalized a rule entitled ''Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care'' (84 FR 51732). This rule was in part motivated by a commitment across CMS and HHS to ''the vision of creating an environment where agencies incorporate and integrate the ongoing retrospective review of regulations into Department operations to achieve a more streamlined and effective regulatory framework.''

One of the major provisions finalized in this rule was the removal of data submission, clinical experience, and outcomes requirements for Medicare re-approval that were previously required of transplant hospitals participating in the Medicare program. As described in the rule, CMS had put in place additional CoPs in the March 2007 final rule (72 FR 15198) in an effort to increase the quality of care by specifying minimal health and safety standards for transplant hospitals. In addition, outcome metrics (1 year graft and patient survival) were included in the regulation and mirrored the OPTN outcomes metrics as calculated by the SRTR.

CMS removed the outcomes requirements for a few key reasons. First, the concern was that transplant centers were also subject to OPTN policies, so parallel regulation on the CMS side was duplicative. Additionally, the concern was that ''increased emphasis on organ and patient survival rates, as key metrics of transplant performance, created incentives for transplant programs to select organs most likely to survive after transplant without rejection, and to select recipients most likely to survive after the transplant.'' This focus had the effect of creating ''performance standards that focused only on organ and patient survival rates for those who received a transplant, not on survival rates of patients awaiting transplant.'' [292]

In December 2021, CMS published an RFI entitled ''Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities'' (86 FR 68594).[293] In this RFI, CMS asked questions about the overall transplant ecosystem, with goal of helping ''to inform potential changes that would create system-wide improvements, which would further lead to improved organ donation, organ transplantation, quality of care in dialysis facilities, and improved access to dialysis services.''

We noted that we were seeking ways to harmonize policies across the

[291] Sumit Mohan, Miko Yu, Kristen L. King, S. Ali Husain, Increasing Discards as an Unintended Consequence of Recent Changes in United States Kidney Allocation Policy, Kidney International Reports, Volume 8, Issue 5, 2023, Pages 1109–1111, ISSN 2468–0249, *https://doi.org/10.1016/j.ekir.2023.02.1081.*

[292] *https://www.federalregister.gov/d/2019-20736/p-87.*

[293] Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities. *https://www.federalregister.gov/documents/2021/12/03/2021-26146/request-for-information-health-and-safety-requirements-for-transplant-programs-organ-procurement.*

primary HHS agencies (CMS, HRSA, and the Food and Drug Administration (FDA)) that are involved in regulating stakeholders in the transplant ecosystem so that our requirements are not duplicative, conflicting, or overly burdensome. We asked if there any current requirements for transplant programs, ESRD facilities, or OPOs that are unnecessarily duplicative of, or in conflict with, OPTN policies or policies that are covered by other government agencies. We also asked about the impacts of these duplicative requirements on organ utilization and transplant program/ESRD facility/OPO quality and efficiency (86 FR 68596).

Given the concerns described in these past efforts, the OPTN has been in part responsive to concerns from interested parties about their metrics and effects and has expanded which metrics they are evaluating transplant centers for their performance. In December 2021, the OPTN approved four new risk-adjusted metrics to be used to monitor transplant program performance, including 90-day graft survival hazard ratio, 1-year conditional graft survival hazard ratio, pre-transplant mortality rate ratio, and offer acceptance ratio.[294] This added two new metrics for areas beyond simply looking at transplant survival, and looked at a more holistic view of patient care for beneficiaries on the transplant list. There is a critical role for both the Department and the OPTN with regard to the transplant ecosystem. The final rule governing the operation of the OPTN from 1996 (63 FR 16296) stated the following:

The Department believes that the transplantation network must be operated by professionals in the transplant community, and that both allocation and other policies of the OPTN should be developed by transplant professionals, in an open environment that includes the public, particularly transplant patients and donor families. It is not the desire or intention of the Department to interfere in the practice of medicine. This rule does not alter the role of the OPTN to use its judgment regarding appropriate medical criteria for organ allocation nor is it intended to circumscribe the discretion afforded to doctors who must make the difficult judgments that affect individual patients. At the same time, the Department has an important and constructive role to play, particularly on behalf of patients. Human organs that are given to save lives are a public resource and a public trust.

We believe that the proposed IOTA Model recognizes the goals of the Department on behalf of the public and the medical judgment exhibited by the OPTN. We believe that constructing this as a model test would enable the Department to test out a different approach to incentivize certain behavior for transplant centers, while also acknowledging the role of the OPTN and transplant professionals in this area.

We note the concern put forward by kidney transplant hospitals that they would not be able to increase their number of transplants without potentially affecting their performance 90 day and 1-year graft survival rate metrics used by the MPSC. However, we believe that there are several different ways that IOTA participants would ultimately be able to succeed under the IOTA Model and OPTN policies:

- The MPSC standard represents a standard far below the national average of performance that should be able to be met by member transplant centers. The MPSC describes this as meaning that to be identified for outcomes review in a document describing their Performance Reviews,[295] ''[t]he adult criteria is based on the likelihood that the program's performance was at least 75 percent worse than an average program, accounting for differences in the types of recipients and donor organs transplanted. The pediatric criterion is based on the likelihood that the program's performance was at least 60 percent worse than an average program, accounting for differences in the types of recipients and donor organs transplanted. Even if a program meets one or both of the criteria for graft survival, the MPSC may not send the program an inquiry based on various situations, such as recent release from review for outcomes or program membership status.'' This represents a minimum standard of care and only a small percentage were flagged for not meeting those standards.
- The IOTA Model incentivizes investment in both living and deceased donor transplants. Living donor transplantation has rates that have been relatively flat for 20 years and has recipients of those organs with better post-transplant outcomes.
- MPSC outcomes metrics are risk adjusted based on organ quality and can account for the use of organs that are currently being discarded.
- Many organs currently being discarded are quality organs. Though the median KDRI of discarded kidneys was higher for discarded kidneys than transplanted kidneys, there is a large overlap in the quality of discarded and transplanted kidneys.[296]
- Per 42 CFR 121.10(c)(1), the reviews conducted by the OPTN result in an advisory opinion to the Secretary of a recommended course of action. The Secretary then has the option under 42 CFR 121.10(c)(2) of requesting additional information, declining to accept the recommendation, accepting the recommendation, or taking such other action as the Secretary deems necessary. Given the enforcement discretion given to the Secretary, the Secretary may take into account performance on the metrics evaluated in the IOTA Model as part of a holistic evaluation of transplant hospital performance.

Additionally, CMS also considered, but is not proposing, a limited waiver of section 1138(a)(1)(B) of the Act as part of the IOTA Model, which requires that a hospital be a member and abide by the rules and requirements of the OPTN. We considered retaining transplant hospitals' membership obligations to the OPTN with the exception of their required responsiveness to MPSC transplant hospital performance reviews and the potential for adverse actions that may risk a transplant hospital's operations and reimbursement by Federal health insurance programs. However, we do not believe that this waiver is necessary for testing the model, and that a transplant hospital can perform on both the metrics put forward by the MPSC and demonstrate successful performance in the IOTA Model.

We invite public comments on our proposals to account for overlaps with other CMS programs and models.

10. Beneficiary Protections

a. Beneficiary Notifications

We propose to require IOTA participants to provide notice to attributed patients that the IOTA participant is participating in the IOTA Model. We believe it would be important for IOTA participants to provide attributed patients with a standardized, CMS-developed, beneficiary notice to limit the potential for fraud and abuse, including patient steering. We intend to provide a notification template that IOTA

[294] *OPTN Board adopts new transplant program performance metrics—OPTN.* (2021, December 16). *Optn.transplant.hrsa.gov*. Retrieved May 30, 2023, from *https://optn.transplant.hrsa.gov/news/optn-board-adopts-new-transplant-program-performance-metrics/.*

[295] *https://optn.transplant.hrsa.gov/media/5j5dov5s/what_to_expect_performance_reviews.pdf.*

[296] Mohan, S., Chiles, M.C., Patzer, R.E., Pastan, S.O., Husain, S.A., Carpenter, D.J., Dube, G.K., Crew, R.J., Ratner, L.E., & Cohen, D.J. (2018). Factors leading to the discard of deceased donor kidneys in the United States. *Kidney International, 94*(1), 187–198. *https://doi.org/10.1016/j.kint.2018.02.016.*

participants would be required to use. This template would, at minimum, indicate content that the IOTA participant would not be permitted to change and would indicate where the IOTA participant could insert its own content. It would also include information regarding the attributed patient's ability to opt-out of data sharing with IOTA participants and how they may opt out if they choose to do so.

We propose requiring IOTA participants to display a notice containing these rights and protections prominently at each office or facility locations where an attributed patient may receive treatment, in a clear manner on its public facing website, and to each attributed patient in a paper format. This would increase the probability that the attributed patients would receive and take note of this information.

We seek comment on the proposed requirements for beneficiary notifications.

b. Availability of Services and Beneficiary Freedom of Choice

If finalized, we propose the Standard Provisions for Innovation Center Models relating to availability of services and beneficiary freedom of choice would apply to the IOTA Model. These provisions were originally finalized as general provisions in the Code of Federal Regulations (42 CFR part 512 subpart A) that applied to specific Innovation Center models, but are separately proposed in this proposed rulemaking in section II.B of this proposed rule for expansion to all Innovation Center Models with performance periods that begin on or after January 1, 2025. Consistent with these proposed provisions, IOTA participants would need to preserve beneficiary freedom of choice and continue to make medically necessary covered services available to beneficiaries to the extent required by applicable law.

11. Financial Arrangements and Attributed Patient Engagement Incentives

a. Background

We believe it is necessary to provide IOTA participants with flexibilities that could support their performance in the IOTA Model and allow for greater support for the needs of attributed patients. These flexibilities are outlined in this section and include the ability to engage in financial arrangements to share IOTA upside risk payments and responsibility for paying Medicare for IOTA downside risk payments with providers and suppliers making contributions to the IOTA participants' performance against model metrics, and the availability of the provision of attributed patient engagement incentives. Such flexibilities would allow IOTA participants to share all or some of the payments they may be eligible to receive from CMS and to share the responsibility for the funds needed to pay CMS providers and suppliers engaged in caring for attributed patients, if those providers and suppliers have a role in the IOTA participant's spending or quality performance. Additionally, we believe that IOTA participants caring for attributed patients may want to offer attributed patient engagement incentives to encourage adherence to recommended treatment and active patient engagement in recovery. These incentives may help an IOTA participant reach their quality and efficiency goals for the model, while also benefitting beneficiaries' health and the Medicare Trust Fund if the IOTA participant improves the quality and efficiency of care that results in the Medicare beneficiary's reductions in hospital readmissions, complications, days in acute care, and mortality, while recovery continues uninterrupted or accelerates.

b. Overview of IOTA Model Financial Arrangements

We believe that IOTA participants may wish to enter into financial arrangements with providers and suppliers caring for attributed patients to share model upside risk payments or downside risk payments, to align the financial incentives of those providers and suppliers with the IOTA Model goals of increasing the number of kidney transplants furnished to attributed patients to lower costs and to improve their quality of life. To do so, we expect that IOTA participants would identify key providers and suppliers caring for attributed patients in their communities and DSAs. The IOTA participants could establish partnerships with these providers and suppliers to promote accountability for the quality, cost, and overall care for attributed patients, including managing and coordinating care; encouraging investment in infrastructure, enabling technologies, and redesigning care processes for high quality and efficient service delivery; and carrying out other obligations or duties under the IOTA Model. These providers and suppliers may invest substantial time and other resources in these activities, yet they would neither be the direct recipients of any model upside risk payments from Medicare, nor directly responsible for paying to CMS any downside risk payments incurred. Therefore, we believe it is possible that an IOTA participant that may receive an upside risk payment from Medicare or may need to pay a downside risk payment to Medicare may want to enter into financial arrangements with other providers or suppliers to share these performance adjustments with the IOTA participant.

We expect that all financial relationships established between IOTA participants and providers or suppliers for purposes of the IOTA Model would only be those permitted under applicable law and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements. As discussed in section III.C.3 of this proposed rule, CMS expects to finalize the proposal that the anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)(1)) is available to protect the financial arrangements proposed in this section when arrangements with eligible providers and suppliers are in compliance with this policy and the conditions for use of the anti-kickback statute safe harbor set out at § 1001.952(ii)(1), if the proposed arrangements are finalized.

We recognize that there are numerous arrangements that IOTA participants may wish to enter other than the financial arrangements described in the regulations for which safe harbor protection may be extended that could be beneficial to the IOTA participants. For example, IOTA participants may choose to engage with organizations that are neither providers nor suppliers to assist with matters such as data analysis; local provider and supplier engagement; care redesign planning and implementation; beneficiary outreach; beneficiary care coordination and management; monitoring IOTA participants' compliance with the model's terms and conditions; or other model-related activities. Such organizations may play important roles in an IOTA participant's plans to implement the model based on the experience these organizations may bring, such as prior experience with living donation initiatives, care coordination expertise, familiarity with a particular local community, or knowledge of SRTR data. We expect that all relationships established between IOTA participants and these organizations for purposes of the model would be those permitted only under existing law and regulation, including any relationships that would include

the IOTA participant's sharing of model upside risk payments or downside risk payments with such organizations. We would expect these relationships to be solely based on the level of engagement of the organization's resources to directly support the participants' model implementation.

c. IOTA Collaborators

Given the financial incentives of the IOTA performance-based payments, as described in section III.C. of this proposed rule, an IOTA participant may want to engage in financial arrangements with providers and suppliers making contributions to the IOTA participant's performance across the achievement domain, efficiency domain, and quality domain. Such arrangements would allow the IOTA participant to share monies earned from the upside risk payments. Likewise, such arrangements could allow the IOTA participant to share the responsibility for the funds needed to repay CMS the downside risk payments. We propose to use the term ''IOTA collaborator'' to refer to these providers and suppliers.

Because attributed patients include both those on the kidney transplant waitlist and those who have received a kidney transplant, as described in section III.C.4.a of this proposed rule, many providers and suppliers other than the IOTA participant would furnish related services to attributed patients during the model performance period. As such, for purposes of the anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR part 1001.952(ii)), we propose that the following types of providers and suppliers that are Medicare-enrolled and eligible to participate in Medicare may be IOTA collaborators:

- Nephrologist.
- ESRD Facility.
- Skilled Nursing Facility (SNF).
- Home Health Agency (HHA).
- Long-Term Care Hospital (LTCH).
- Inpatient Rehabilitation Facility (IRF).
- Physician.
- Nonphysician practitioner.
- Therapist in a private practice.
- Comprehensive Outpatient Rehabilitation Facility (CORF).
- Provider or supplier of outpatient therapy services.
- Physician Group Practice (PGP).
- Hospital.
- Critical Access Hospital (CAH).
- Non-physician provider group practice (NPPGP).
- Therapy Group Practice (TGP).

We seek comment on the proposed definition of IOTA collaborators and any additional Medicare-enrolled providers or suppliers that should be included in this definition.

d. Sharing Arrangements

(1) General

Similar to the Comprehensive Care for Joint Replacement Payment Model (CJR) (42 CFR part 510), we propose that certain financial arrangements between an IOTA participant and an IOTA collaborator be termed ''sharing arrangements.'' For purposes of the anti-kickback statute safe harbor for CMS-sponsored model arrangements (§ 1001.952(ii)(1)), we propose that a sharing arrangement would be a financial arrangement to share only—(1) the upside risk payment; and (2) the downside risk payment.

Where a payment from an IOTA participant to an IOTA collaborator is made pursuant to a sharing arrangement, we define that payment as a ''gainsharing payment,'' which is discussed in section III.C.11.d.(3). of this proposed rule. Where a payment from an IOTA collaborator to an IOTA participant is made pursuant to a sharing arrangement, we define that payment as an ''alignment payment,'' which is discussed in section III.C.11.d.(3). of this proposed rule.

(2) Requirements

We propose several requirements for sharing arrangements to help ensure that their sole purpose is to create financial alignment between IOTA participants and IOTA collaborators toward the goals of the model while maintaining adequate program integrity safeguards. An IOTA participant must not make a gainsharing payment or receive an alignment payment except in accordance with a sharing arrangement. We propose that a sharing arrangement must comply with the provisions of § 512.452 and all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.

We propose that the IOTA participant must develop, maintain, and use a set of written policies for selecting providers and suppliers to be IOTA collaborators. To safeguard against potentially fraudulent or abusive practices, we propose that the selection criteria must include the quality of care delivered by the potential IOTA collaborator. We also propose that the selection criteria cannot be based directly or indirectly on the volume or value of referrals or business otherwise generated by, between, or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent. Additionally, we propose that IOTA participants must consider the selection of IOTA collaborators based on criteria related to, and inclusive of, the anticipated contribution to the performance of the IOTA participant across the achievement domain, efficiency domain, and quality domain by the potential IOTA collaborator to ensure that the selection of IOTA collaborators takes into consideration the likelihood of their future performance.

It is necessary that IOTA participants have adequate oversight over sharing arrangements to ensure that all arrangements meet the requirements of this section. Therefore, we propose that the board or other governing body of the IOTA participant have responsibility for overseeing the IOTA participant's participation in the model, including, but not limited to: its arrangements with IOTA collaborators, its payment of gainsharing payments, its receipt of alignment payments, and its use of beneficiary incentives (as discussed in III.C.11.h of this proposed rule).

Finally, we propose that if an IOTA participant enters a sharing arrangement, its compliance program must include oversight of sharing arrangements and compliance with the applicable requirements of the model. Requiring oversight of sharing arrangements to be included in the compliance program provides a program integrity safeguard.

We seek comment about all provisions described in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

We propose that the sharing arrangement must be in writing, signed by the parties, and entered into before care is furnished to attributed patients during the PY under the sharing arrangement. In addition, participation in the sharing arrangement must require the IOTA collaborator to comply with the requirements of this model, as those pertain to their actions and obligations. Participation in a sharing arrangement must be voluntary and without penalty for nonparticipation. It is important that providers and suppliers rendering items and services to attributed patients during the model performance period have the freedom to provide medically necessary items and services to attributed patients without any requirement that they participate in a sharing arrangement to safeguard

beneficiary freedom of choice, access to care, and quality of care. The sharing arrangement must set out the mutually agreeable terms for the financial arrangement between the parties to guide and reward model care redesign for future performance across the achievement domain, efficiency domain, and quality domain, rather than reflect the results of model PYs that have already occurred and where the financial outcome of the sharing arrangement terms would be known before signing.

We propose that the sharing arrangement must require the IOTA collaborator and its employees, contractors (including collaboration agents), and subcontractors to comply with certain requirements that are important for program integrity under the arrangement. We note that the terms contractors and subcontractors, respectively, include collaboration agents as defined later in this section. The sharing arrangement must require all of the individuals and entities in this group to comply with the applicable provisions of §§ 512.450–512.466 of this proposed rule, including requirements regarding beneficiary notifications, access to records, record retention, and participation in any evaluation, monitoring, compliance, and enforcement activities performed by CMS or its designees, because these individuals and entities all would play a role in model care redesign and be part of financial arrangements under the model. The sharing arrangement must also require all individuals and entities in the group to comply with the applicable Medicare provider enrollment requirement at § 424.500 *et seq.,* including having a valid and active TIN or NPI, during the term of the sharing arrangement. This is to ensure that these individuals and entities have the required enrollment relationship with CMS under the Medicare program, although we note that they are not responsible for complying with requirements that do not apply to them. Finally, the sharing arrangement must require these individuals and entities to comply with all other applicable laws and regulations.

We propose that the sharing arrangement must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care so that financial relationships between IOTA participants and IOTA collaborators do not negatively impact beneficiary protections under the model. The sharing arrangement must require the IOTA collaborator to have, or be covered by, a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the IOTA Model that apply to its role as an IOTA collaborator, including any distribution arrangements, just as we require IOTA participants to have a compliance program that covers oversight of the sharing arrangement for this purpose as a program integrity safeguard. We seek comment on the anticipated effect of the proposed compliance program requirement for IOTA collaborators, particularly with regard to individual physicians and nonphysician practitioners, small PGPs, NPPGPs, and TGPs and whether alternative compliance program requirements for all or a subset of IOTA collaborators should be adopted to mitigate any effect of the proposal that could make participation as an IOTA collaborator infeasible for any provider, supplier, or other entity on the proposed list of types of IOTA collaborators.

For purposes of sharing arrangements under the model, we propose to define activities related to promoting accountability for the quality, cost, and overall care for attributed patients and performance across the achievement domain, efficiency domain, and quality domain, including managing and coordinating care; encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery; the provision of items and services pre or post-transplant in a manner that reduces costs and improves quality; or carrying out any other obligation or duty under the model as ''IOTA activities.'' In addition to the quality of episodes of care, we believe the activities that would fall under this proposed definition could encompass the totality of activities upon which it would be appropriate for sharing arrangements to value the contributions of collaborators and collaboration agents toward meeting the performance goals of the model. We seek comment on the proposed definition of IOTA activities as an inclusive and comprehensive framework for capturing direct care and care redesign that contribute to performance across the achievement domain, efficiency domain, and quality domain.

We propose that the written sharing arrangement agreement must specify the following parameters of the arrangement:

- The purpose and scope of the sharing arrangement.
- The identities and obligations of the parties, including specified IOTA activities and other services to be performed by the parties under the sharing arrangement.
- The date of the sharing arrangement.
- Management and staffing information, including type of personnel or contractors that would be primarily responsible for carrying out IOTA activities.
- The financial or economic terms for payment, including all of the following:

++ Eligibility criteria for a gainsharing payment.

++ Eligibility criteria for an alignment payment.

++ Frequency of gainsharing or alignment payment.

++ Methodology and accounting formula for determining the amount of a gainsharing payment that is substantially based on performance across the achievement domain, efficiency domain and quality domain, and the provision of IOTA Model activities.

++ Methodology and accounting formula for determining the amount of an alignment payment.

Finally, we propose to require that the terms of the sharing arrangement must not induce the IOTA participant, IOTA collaborator, or any employees, contractors, or subcontractors of the IOTA participant or IOTA collaborator to reduce or limit medically necessary services to any attributed patient or restrict the ability of an IOTA collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies, and treatments. These requirements are to ensure that the quality of care for attributed patients is not negatively affected by sharing arrangements under the model.

The proposals for the requirements for sharing arrangements under the model are included in § 512.452.

We seek comment about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

(3) Gainsharing Payments and Alignment Payments

We propose several conditions and limitations for gainsharing payments and alignment payments as program integrity protections for the payments to and from IOTA collaborators. We propose to require that gainsharing payments be derived solely from upside risk payments; that they be distributed on an annual basis, not more than once per calendar year; that they not be a loan, advance payment, or payment for referrals or other business; and that they

be clearly identified as a gainsharing payment at the time they are paid.

We believe that gainsharing payment eligibility for IOTA collaborators should be conditioned on two requirements—(1) contributing to performance across the achievement domain, efficiency domain or quality domain; and (2) rendering items and services to attributed patients during the model performance period—as safeguards to ensure that eligibility for gainsharing payments is solely based on aligning financial incentives for IOTA collaborators with the performance metrics of the model. With respect to the first requirement, we propose that to be eligible to receive a gainsharing payment, an IOTA collaborator must contribute to the performance of the IOTA participant across the achievement domain, efficiency domain or quality domain during the PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment. We also propose that the contribution to performance across the achievement domain, efficiency domain, or quality domain criteria must be established by the IOTA participant and directly related to the care of attributed patients. With regard to the second requirement, to be eligible to receive a gainsharing payment, or to be required to make an alignment payment, an IOTA collaborator other than a PGP, NPPGP, or TGP must have directly furnished a billable item or service to an attributed patient during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment or incurred a downside risk payment. For purposes of this requirement, we consider a hospital, CAH or post-acute care provider to have ''directly furnished'' a billable service if one of these entities billed for an item or service for an attributed patient in the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment or incurred a downside risk payment. The phrase ''PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment or incurred a downside risk payment'' does not mean the year in which the gainsharing payment was made. These requirements ensure that there is a required relationship between eligibility for a gainsharing payment and the direct care for attributed patients during PY for these IOTA collaborators. We believe the provision of direct care is essential to the implementation of effective care redesign, and the requirement provides a safeguard against payments to IOTA collaborators other than a PGP, NPPGP, or TGP that are unrelated to direct care for attributed patients during the model performance period.

We propose to establish similar requirements for IOTA collaborator's that are PGPs, NPPGPs and TGPs that vary because these entities do not themselves directly furnish billable services. To be eligible to receive a gainsharing payment or required to make an alignment payment, a PGP, NPPGP or TGP must have billed for an item or service that was rendered by one or more members of the PGP, NPPGP or TGP to an attributed patient the same PY for which the IOTA participant earned an upside risk payment that comprises the gainsharing payment or incurred a downside risk payment. Like the proposal for IOTA collaborators that are not PGPs, NPPGPs or TGPs, these proposals also require a link between the IOTA collaborator that is the PGP, NPPGP or TGP and the provision of items and services to attributed patients during the PY by PGP, NPPGP or TGP members.

Moreover, we further propose that, because PGPs, NPPGPs and TGPs do not directly furnish items and services to patients, to be eligible to receive a gainsharing payment or be required to make an alignment payment, the PGP, NPPGP or TGP must have contributed to IOTA activities and been clinically involved in the care of attributed patients during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment or incurred a downside risk payment. For example, a PGP, NPPGP, or TGP could have contributed to IOTA activities and been clinically involved in the care of attributed patients if they—

- Provided care coordination services to attributed patients during and after inpatient admission;
- Engaged with an IOTA participant in care redesign strategies, and performed a role in the implementation of such strategies, that were designed to improve the quality of care for attributed patients; or
- In coordination with other providers and suppliers (such as PGP members, NPPGP members, or TGP members; the IOTA participant; and post-acute care providers), implemented strategies designed to address and manage the comorbidities of attributed patients.

We propose to limit the total amount of gainsharing payments for a PY to IOTA collaborators that are physicians, nonphysician practitioners, PGPs, NPPGPs or TGPs. For IOTA collaborators that are physicians or nonphysician practitioners, that limit is 50 percent of the Medicare-approved amounts under the PFS for items and services furnished by that physician or nonphysician practitioner to the IOTA participant's attributed patients during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being made. For IOTA collaborators that are PGPs, NPPGPs or TGPs that limit is 50 percent of the Medicare-approved amounts under the PFS for items and services billed by the PGP, NPPGP or TGP and furnished to the IOTA participant's attributed patients by members of the PGP, NPPGP or TGP during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being made. These limits are consistent with those in the CJR model.

We propose that the amount of any gainsharing payments must be determined in accordance with a methodology that is substantially based on contribution to performance across the achievement domain, efficiency domain, and quality domain and the provision of IOTA activities. The methodology may take into account the amount of such IOTA activities provided by an IOTA collaborator relative to other IOTA collaborators. While we emphasize that financial arrangements may not be conditioned directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent so that their sole purpose is to align the financial incentives of the IOTA participant and IOTA collaborators toward the model, we believe that accounting for the relative amount of IOTA activities by IOTA collaborators in the determination of gainsharing payments does not undermine this objective. Rather, the proposed requirement allows flexibility in the determination of gainsharing payments where the amount of an IOTA collaborator's provision of IOTA activities (including direct care) to attributed patients during the model performance period may contribute to the IOTA participant's upside risk payment that may be available for making a gainsharing payment. Greater contributions of IOTA activities by one IOTA collaborator versus that result in greater differences in the funds available for gainsharing payments may be

appropriately valued in the methodology used to make gainsharing payments to those IOTA collaborators to reflect these differences in IOTA activities among them. For example, a physician who is an IOTA collaborator who treats 20 attributed patients during the PY that result in high quality, less costly care could receive a larger gainsharing payment than a physician who is an IOTA collaborator who treats 10 attributed patients during episodes that similarly result in high quality, less costly care.

However, we do not believe it would be appropriate to allow the selection of IOTA collaborators or the opportunity to make or receive a gainsharing payment or an alignment payment to take into the account the amount of IOTA activities provided by a potential or actual IOTA collaborator relative to other potential or actual IOTA collaborators because these financial relationships are not to be based directly or indirectly on the volume or value of referrals or business otherwise generated by, between, or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent. Specifically, with respect to the selection of IOTA collaborators or the opportunity to make or receive a gainsharing payment or an alignment payment, we do not believe that the amount of model activities provided by a potential or actual IOTA collaborator relative to other potential or actual IOTA collaborators could be taken into consideration by the IOTA participant without a significant risk that the financial arrangement in those instances could be based directly or indirectly on the volume or value of referrals or business generated by, between or among the parties. Similarly, if the methodology for determining alignment payments was allowed to take into the account the amount of IOTA activities provided by an IOTA collaborator relative to other IOTA collaborators, there would be a significant risk that the financial arrangement could directly account for the volume or value of referrals or business generated by, between, or among the parties and, therefore, we propose that the methodology for determining alignment payments may not directly take into account the volume or value of referrals or business generated by, between or among the parties.

We seek comment on this proposal for gainsharing payments, where the methodology could take into account the amount of IOTA activities provided by an IOTA collaborator relative to other IOTA collaborators. We are particularly interested in comments about whether this standard would provide sufficient additional flexibility in the gainsharing payment methodology to allow the financial reward of IOTA collaborators commensurate with their level of effort that achieves model goals. In addition, we are interested in comment on whether additional safeguards or a different standard is needed to allow for greater flexibility to provide certain performance-based payments consistent with the goals of program integrity, protecting against abuse and ensuring the goals of the model are met.

We propose that for each PY, the aggregate amount of all gainsharing payments that are derived from an upside risk payment must not exceed the amount of the upside risk payment paid by CMS. In accordance with the prior discussion, no entity or individual, whether a party to a sharing arrangement or not, may condition the opportunity to make or receive gainsharing payments or to make or receive alignment payments, directly or indirectly, on the volume or value of referrals or business otherwise generated by, between, or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent. We propose that an IOTA participant must not make a gainsharing payment to an IOTA collaborator that is subject to any action for noncompliance with this part or the fraud and abuse laws, or for the provision of substandard care to attributed patients or other integrity problems. Finally, the sharing arrangement must require the IOTA participant to recoup any gainsharing payment that contained funds derived from a CMS overpayment on an upside risk payment or was based on the submission of false or fraudulent data. These requirements provide program integrity safeguards for gainsharing under sharing arrangements.

With respect to alignment payments, we propose that alignment payments from an IOTA collaborator to an IOTA participant may be made at any interval that is agreed upon by both parties. We propose that alignment payments must not be issued, distributed, or paid prior to the calculation by CMS of a payment amount reflected in a notification of the downside risk payment; loans, advance payments, or payments for referrals or other business; or assessed by an IOTA participant if the IOTA participant does not owe a downside risk payment. The IOTA participant must not receive any amounts under a sharing arrangement from an IOTA collaborator that are not alignment payments.

We also propose certain limitations on alignment payments that are consistent with the CJR Model. For a PY, the aggregate amount of all alignment payments received by the IOTA participant must not exceed 50 percent of the IOTA participant's downside risk payment. Given that the IOTA participant would be responsible for developing and coordinating care redesign strategies in response to its IOTA participation, we believe it is important that the IOTA participant retain a significant portion of its responsibility for payment to CMS. For example, upon receipt of a notification indicating that the IOTA participant owes a downside risk payment of $100 to CMS, the IOTA participant would be permitted to receive no more than $50 in alignment payments, in the aggregate, from its IOTA collaborators. In addition, the aggregate amount of all alignment payments from a single IOTA collaborator to the IOTA participant may not be greater than 25 percent of the IOTA participant's downside risk payment over the course of a single PY for an IOTA collaborator. We seek comment on our proposed aggregate and individual IOTA collaborator limitations on alignment payments.

We propose that all gainsharing payments and any alignment payments must be administered by the IOTA participant in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book). Additionally, we propose that all gainsharing payments and alignment payments must be made by check, electronic funds transfer (EFT), or another traceable cash transaction. We seek comment on the effect of this proposal.

The proposals for the conditions and restrictions on gainsharing payments and alignment payments under the model are included in § 512.452.

We seek comment about all of the conditions and restrictions set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

(4) Documentation Requirements

To ensure the integrity of the sharing arrangements, we propose that IOTA participants must meet a variety of documentation requirements for these arrangements. Specifically, the IOTA participant must—

• Document the sharing arrangement contemporaneously with the establishment of the arrangement;
• Maintain accurate current and historical lists of all IOTA collaborators, including IOTA collaborator names and addresses. Specifically, the IOTA participant must—
++ Update such lists on at least a quarterly basis; and
++ Publicly report the current and historical lists of IOTA collaborators and any written policies for selecting individuals and entities to be IOTA collaborators required by the IOTA participant on a web page on the IOTA participants website; and
• Maintain and require each IOTA collaborator to maintain contemporaneous documentation with respect to the payment or receipt of any gainsharing payment or alignment payment that includes at a minimum the—
++ Nature of the payment (gainsharing payment or alignment payment);
++ Identity of the parties making and receiving the payment;
++ Date of the payment;
++ Amount of the payment;
++ Date and amount of any recoupment of all or a portion of an IOTA collaborator's gainsharing payment; and
++ Explanation for each recoupment, such as whether the IOTA collaborator received a gainsharing payment that contained funds derived from a CMS overpayment of an upside risk payment, or was based on the submission of false or fraudulent data.

In addition, we propose that the IOTA participant must keep records for all of the following:
• Its process for determining and verifying its potential and current IOTA collaborators' eligibility to participate in Medicare;
• A description of current health information technology, including systems to track upside risk payments and downside risk payments; and
• Its plan to track gainsharing payments and alignment payments.

Finally, we propose that the IOTA participant must retain and provide access to, and must require each IOTA collaborator to retain and provide access to, the required documentation in accordance with § 512.460 and § 1001.952(ii).

The proposals for the requirements for documentation of sharing arrangements under the model are included in § 512.452(d).

We seek comment about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

e. Distribution Arrangements

(1) General

Similar to the CJR Model, we propose that certain financial arrangements between IOTA collaborators and other individuals or entities called ''collaboration agents'' be termed ''distribution arrangements.'' For purposes of the anti-kickback statute safe harbor for CMS-sponsored model arrangements (§ 1001.952(ii)(1)), we propose to define ''distribution arrangement'' as a financial arrangement between an IOTA collaborator that is a PGP, NPPGP or TGP and a collaboration agent for the sole purpose of sharing a gainsharing payment received by the PGP, NPPGP or TGP. We propose to define ''collaboration agent'' as an individual or entity that is not an IOTA collaborator and that is a member of a PGP, NPPGP, or TGP that has entered into a distribution arrangement with the same PGP, NPPGP, or TGP in which he or she is an owner or employee, and where the PGP, NPPGP, or TGP is an IOTA collaborator. Where a payment from an IOTA collaborator that is an PGP, NPPGP, or TGP is made to a collaboration agent, under a distribution arrangement, composed only of gainsharing payments, we propose to define that payment as a ''distribution payment.'' We propose that a collaboration agent could only make a distribution payment in accordance with a distribution arrangement that complies with the provisions of § 512.454 and all other applicable laws and regulations, including the fraud and abuse laws.

The proposals for the general provisions for distribution arrangements under the model are included in § 512.454.

We seek comment about all of the provisions set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

(2) Requirements

We propose a number of specific requirements for distribution arrangements as a program integrity safeguard to help ensure that their sole purpose is to create financial alignment between IOTA collaborators and collaboration agents and performance across the achievement domain, efficiency domain, and quality domain. These requirements largely parallel those proposed in § 512.452 for sharing arrangements and gainsharing payments based on similar reasoning for these two types of arrangements and payments. We propose that all distribution arrangements must be in writing and signed by the parties, contain the date of the agreement, and be entered into before care is furnished to attributed patients under the distribution arrangement. Furthermore, we propose that participation must be voluntary and without penalty for nonparticipation, and the distribution arrangement must require the collaboration agent to comply with all applicable laws and regulations.

Like our proposal for gainsharing payments, we propose that the opportunity to make or receive a distribution payment must not be conditioned directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent. We propose more flexible standards for the determination of the amount of distribution payments from PGPs, NPPGPs and TGPs for the same reasons we propose this standard for the determination of gainsharing payments.

We note that for distribution payments made by a PGP to PGP members, by NPPGPs to NPPGP members, or TGPs to TGP members, the requirement that the amount of any distribution payments must be determined in accordance with a methodology that is substantially based on performance across the achievement domain, efficiency domain, and quality domain and the provision of IOTA Model activities may be more limiting in how a PGP pays its members than is allowed under existing law. Therefore, to retain existing flexibility for distribution payments by a PGP to PGP members, we propose that the amount of the distribution payment from a PGP to PGP members must be determined in a manner that complies with § 411.352(g). This proposal would allow a PGP the choice either to comply with the general standard that the amount of a distribution payment must be substantially based on contribution to the performance across the achievement domain, efficiency domain, and quality domain and the provision of IOTA Model activities or to provide its members a financial benefit through the model without consideration of the PGP member's individual contribution to the performance across the achievement

domain, efficiency domain and quality domain. In the latter case, PGP members that are not collaboration agents (including those who furnished no services to attributed patients) would be able receive a share of the profits from their PGP that includes the monies contained in a gainsharing payment. We believe this is an appropriate exception to the general standard for determining the amount of distribution payment under the model from a PGP to a PGP member, because CMS has determined under the physician self-referral law that payments from a group practice as defined under § 411.352 to its members that comply with § 411.352(g) are appropriate.

We seek comment on this proposal and specifically whether there are additional safeguards or a different standard is needed to allow for greater flexibility in calculating the amount of distribution payments that would avoid program integrity risks and whether additional or different safeguards are reasonable, necessary, or appropriate for the amount of distribution payments from a PGP to its members, a NPPGP to its members or a TGP to its members.

Similar to our proposed requirements for sharing arrangements for those IOTA collaborators that furnish or bill for items and services, except for a distribution payment from a PGP to a PGP member that complies with § 411.352(g), we propose that a collaboration agent is eligible to receive a distribution payment only if the collaboration agent furnished or billed for an item or service rendered to an attributed patients during the same PY for which the IOTA participant earned the upside risk payment. We note that all individuals and entities that fall within our proposed definition of collaboration agent may either directly furnish or bill for items and services rendered to attributed patients. This proposal ensures that, absent the alternative safeguards afforded by a PGP's distribution payments in compliance with § 411.352(g), there is the same required relationship between direct care for attributed patients during the PY and distribution payment eligibility that we require for gainsharing payment eligibility. We believe this requirement provides a safeguard against payments to collaboration agents that are unrelated to direct care for attributed patients during the PY when the amount of the distribution payment is not determined in a manner that complies with § 411.352(g).

Except for a distribution payment from a PGP to a PGP member that complies with § 411.352(g), we propose the same limitations on the total amount of distribution payments to physicians, nonphysician practitioners, PGPs, NPPGPs and TGPs as we propose for gainsharing payments. In the case of a collaboration agent that is a physician or nonphysician practitioner, we propose to limit the total amount of distribution payments paid for a PY to the collaboration agent to 50 percent of the total Medicare-approved amounts under the PFS for items and services furnished by the collaboration agent to the IOTA participant's attributed patients during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being distributed. In the case of a collaboration agent that is a group practice, we propose that the limit would be 50 percent of the total Medicare-approved amounts under the PFS for items and services billed by the group practice for items and services furnished by members of the group practice to the IOTA participant's attributed patients during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being distributed. We believe that, absent the alternative safeguards afforded by a group practice's distribution payments in compliance with § 411.352(g), these proposed limitations on distribution payments, which are the same as those for gainsharing payments to physicians, nonphysician practitioners, and group practices, are necessary to eliminate any financial incentives for these individuals or entities to engage in a financial arrangement as an IOTA collaborator versus as a collaboration agent. Furthermore, we believe that group practices should be able to choose whether to engage in financial arrangements directly with IOTA participants as IOTA collaborators without having a different limit on their maximum financial gain from one arrangement versus another.

We further propose that with respect to the distribution of any gainsharing payment received by a PGP, NPPGP or TGP, the total amount of all distribution payments must not exceed the amount of the gainsharing payment received by the IOTA collaborator from the IOTA participant. Like gainsharing and alignment payments, we propose that all distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction. The collaboration agent must retain the ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments. Finally, the distribution arrangement must not induce the collaboration agent to reduce or limit medically necessary items and services to any Medicare beneficiary or reward the provision of items and services that are medically unnecessary.

We propose that the IOTA collaborator must maintain contemporaneous documentation regarding distribution arrangements in accordance with § 512.454, including—

- The relevant written agreements;
- The date and amount of any distribution payment(s);
- The identity of each collaboration agent that received a distribution payment; and
- A description of the methodology and accounting formula for determining the amount of any distribution payment.

We propose that the IOTA collaborator may not enter into a distribution arrangement with any individual or entity that has a sharing arrangement with the same IOTA participant. This proposal ensures that the proposed separate limitations on the total amount of gainsharing payment and distribution payment to PGPs, NPPGPs, TGPs, physicians, and nonphysician practitioners that are substantially based on performance across the achievement domain, efficiency domain, and quality domain and the provision of IOTA activities are not exceeded in absolute dollars by a PGP, NPPGP, TGP, physician, or nonphysician practitioner's participation in both a sharing arrangement and distribution arrangement for the care of the same IOTA beneficiaries during the PY. Allowing both types of arrangements for the same individual or entity for care of the same attributed patients during the PY could also allow for duplicate counting of the individual or entity's same contribution to the achievement domain, efficiency domain, and quality domain and provision of IOTA Model activities in the methodologies for both gainsharing and distribution payments, leading to financial gain that is disproportionate to the contribution to the achievement domain, efficiency domain and quality domain and provision of IOTA Model activities by that individual or entity. Finally, we propose that the IOTA collaborator must retain and provide access to, and must require collaboration agents to retain and provide access to, the required documentation in accordance with § 512.460.

The proposals for requirements for distribution arrangements under the model are included in § 512.454.

We seek comment about all of the requirements set out in the preceding

discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met. In addition, we seek comment on how the regulation of the financial arrangements under this proposal may interact with how these or similar financial arrangements are regulated under the Medicare Shared Savings Program.

f. Enforcement Authority

OIG authority is not limited or restricted by the provisions of the model, including the authority to audit, evaluate, investigate, or inspect the IOTA participant, IOTA collaborators, collaboration agents, or any other person or entity or their records, data, or information, without limitations. Additionally, no model provisions limit or restrict the authority of any other Government Agency to do the same. The proposals for enforcement authority under the model are included in § 512.455.

We seek comment about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

h. Attributed Patient Engagement Incentives

We believe it is necessary and appropriate to provide additional flexibilities to IOTA participants for purposes of testing the IOTA Model to give IOTA participants additional access to the tools necessary to improve attributed patients' access to kidney transplants and ensure attributed patients receive comprehensive and patient-centered post-transplant care. As discussed in section III.C.11.i. of this proposed rule, CMS expects to make a determination that the anti-kickback statute safe harbor for CMS-sponsored model patient incentives is available to protect Part B and Part D immunosuppressive drug cost sharing support and attributed patient engagement incentives proposed in this section when the incentives are offered in compliance with this policy, specifically the conditions for use of the anti-kickback statute safe harbor set out at § 1001.952(ii)(2), if the proposed Part B and Part D immunosuppressive drug cost sharing support policy and attributed patient engagement incentives are finalized.

(1) Part B and Part D Immunosuppressive Drug Cost Sharing Support

The cost of immunosuppressive drugs is a financial burden for many transplant recipients, particularly those without sufficient health insurance coverage.[297] A person's ability to pay for immunosuppressive drugs, among other services needed in the perioperative and postoperative periods, is a factor used by transplant hospitals to assess suitability for the transplant waitlist.[298] Studies have found that low income status decreases the likelihood of waitlisting.[299] One survey of a transplant programs found that 67.3 percent of programs surveys reported frequent or occasional failure to list patients due to concerns regarding ability to pay for immunosuppressive medications.[300] In assessing the financial implications of extending Medicare coverage of immunosuppressive drugs for the lifetime of the patient, the Assistant Secretary for Planning and Evaluation (ASPE) assumed a non-adherence graft failure rate of 10.7 percent and assessed that factors outside of affordability had minimal impact on non-adherence to immunosuppressive drugs.[301]

Between 2016 and 2019, immunosuppressive drugs represented the greatest proportion of drug expenditures in the year following kidney transplant in Medicare Parts B and D.[302] Between 2016 and 2019, the Per-Patient-Per-Year expenditure in the year following transplant in Medicare Parts B and D was $6,947.[303] Medicare beneficiaries whose immunosuppressive drugs are covered by Part B are responsible for 20 percent of these costs. The cost sharing obligation of Medicare beneficiaries whose immunosuppressive drugs are covered by Part D can vary depending on the benefit structure of the Part D plan.

We propose to allow IOTA participants to subsidize, in whole or in part, the cost sharing associated with immunosuppressive drugs covered by Part B, the Part B–ID benefit, and Part D (''Part B and Part D immunosuppressive drug cost sharing support'') incurred by attributed patients. As discussed in section III.C.11.i. of this proposed rule, if this rule is finalized, CMS expects to make a determination that the anti-kickback statute safe harbor for CMS-sponsored model patient incentives (§ 1001.952(ii)(2)) is available to protect the reduction of cost sharing obligations that are made in compliance with this policy and the conditions for use of the anti-kickback statute safe harbor set out at § 1001.952(ii)(2).

We expect that a large proportion of an IOTA participant's attributed patient population would be Medicare ESRD beneficiaries, covered either by traditional Medicare or by MA. Most ESRD beneficiaries covered by traditional Medicare receive immunosuppressive drug coverage through Part B. A proportion of ESRD beneficiaries who are not eligible for Part A at the time of the kidney transplant or who receive a kidney transplant in a non-Medicare approved facility receive immunosuppressive drugs through Medicare Part D. ESRD beneficiaries covered by MA receive Part B immunosuppressive drugs through the plan in which the beneficiary is enrolled.

To be eligible for Part B and Part D immunosuppressive drug cost sharing support, we are proposing to define eligible attributed patient as an attributed patient that receives immunosuppressive coverage through Part B or Part D but that does not have secondary insurance that could provide cost sharing support. An IOTA participant's attributed patient population could include several subsets of eligible attributed patients. One subset of eligible attributed patients could be ESRD beneficiaries who are not able to purchase secondary insurance due to State laws that do not require insurers to sell Medigap plans to Medicare Beneficiaries under the age of 65. Another subset of eligible attributed

[297] James, A., & Mannon, R.B. (2015). The Cost of Transplant Immunosuppressant Therapy: Is This Sustainable? *Current Transplantation Reports, 2*(2), 113–121. *https://doi.org/10.1007/s40472-015-0052-y.*

[298] *The kidney transplant waitlist.* (n.d.). Transplant Living. *https://transplantliving.org/kidney/the-kidney-transplant-waitlist/.*

[299] Park, C., Jones, M.-M., Kaplan, S., Koller, F.L., Wilder, J.M., Boulware, L.E., & McElroy, L.M. (2022). A scoping review of inequities in access to organ transplant in the United States. *International Journal for Equity in Health, 21*(1). *https://doi.org/10.1186/s12939-021-01616-x.*

[300] Evans, R.W., Applegate, W.H., Briscoe, D.M., Cohen, D.J., Rorick, C.C., Murphy, B.T., & Madsen, J.C. (2010). Cost-related immunosuppressive medication nonadherence among kidney transplant recipients. *Clinical Journal of the American Society of Nephrology, 5*(12), 2323–2328. *https://doi.org/10.2215/cjn.04220510.*

[301] *Assessing the Costs and Benefits of Extending Coverage of Immunosuppressive Drugs under Medicare.* (n.d.). ASPE. *https://aspe.hhs.gov/reports/assessing-costs-benefits-extending-coverage-immunosuppressive-drugs-under-medicare.*

[302] United States Renal Data System. (2022). 2022 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. *https://usrds-adr.niddk.nih.gov/2022.*

[303] Ibid.

patients could, under certain conditions, be ESRD beneficiaries whose eligibility for Medicare only due to ESRD ends 36 months following a kidney transplant. Attributed patients whose eligibility for Medicare due to ESRD ends 36 months following a kidney transplant may be eligible for the Medicare Part B Immunosuppressive Drug Benefit (Part B–ID) depending on the availability of other health coverage options such as Medicaid, plans purchased via a State health exchange, or the TRICARE for Life program. Other attributed patients whose Medicare eligibility due to ESRD concludes 36 months following a transplant could choose to return to work and receive immunosuppressive drug coverage through an Employer Group Health Plan (EGHP), enroll in a Qualified health plan (QHP) under the Affordable Care Act as defined by 45 CFR 155.20, or receive coverage through Medicaid. These attributed patients would not be eligible for Part B and Part D immunosuppressive drug cost sharing support. We believe that Part B and Part D immunosuppressive drug cost sharing support would have special value for attributed patients whose Medicare eligibility due only to ESRD ends after 36 months and who are eligible for Medicare Savings Programs (MSPs) but who live in States that have not expanded Medicaid eligibility for adults to include certain individuals with incomes up to 138 percent of the Federal Poverty Level (FPL). These individuals may have incomes that are too high to qualify for Medicaid, but too low to qualify for advance premium tax credits (APTCs) or cost-sharing reductions (CSRs) that would allow them to purchase a QHP. We are not proposing that Part B and Part D immunosuppressive drug cost sharing support would count towards an eligible attributed patients' Part D True Out-of-Pocket (TrOOP). Part B and Part D immunosuppressive drug cost sharing support would be reported on the Prescription Drug Event (PDE) record as Patient Liability Reduction due to Other Payer Amount (PLRO).

We are proposing to allow IOTA participants to subsidize, in whole or in part, the cost sharing associated with immunosuppressive drugs covered by Part B, the Part B–ID benefit, and Part D because we believe cost sharing associated with medically necessary immunosuppressive drugs would represent a significant out-of-pocket cost burden to attributed patients who receive immunosuppressive coverage through Part B, the Part B–ID benefit, or Part D, and because we believe an IOTA participant's attributed patient population would include beneficiaries whose immunosuppressive drugs are covered through each of these avenues (that is, Part B, the Part B–ID benefit, and Part D).

We are proposing several safeguards for the proposed Part B and Part D immunosuppressive drug cost sharing support policy. First, an attributed patient must be eligible to receive cost sharing support under the Part B and Part D cost sharing support policy. IOTA participants must provide a written policy for Part B and Part D immunosuppressive drug cost sharing support in a form and manner determined by CMS that is approved by CMS prior to the PY in which the cost sharing support would be available and prior to offering attributed patients the incentive. An IOTA participant would be required to revalidate the written policy with CMS in a form and manner determined by CMS prior to each PY in which Part B and Part D immunosuppressive drug cost sharing support would be offered subsequently. The initial written policy and the policy that would be revalidated by CMS must establish and justify the criteria that qualify an eligible attributed patient to receive Part B and Part D immunosuppressive drug cost sharing support. In providing the written policy and the revalidation of the written policy for Part B and Part D immunosuppressive drug cost sharing support, the IOTA participant must attest that the IOTA participant will not, in providing Part B and Part D immunosuppressive drug cost sharing support, take into consideration the type, cost, generic status, or manufacturer of the immunosuppressive drug(s) or limit an eligible attributed patient's choice of pharmacy. We believe these policies are necessary to ensure that an IOTA participant would have a sound basis for determining eligibility requirements for Part B and Part D immunosuppressive drug cost sharing support.

We are proposing safeguards to protect against an IOTA participant preferentially providing cost sharing support for certain immunosuppressive drugs. An IOTA participant must not take into consideration the type, cost, generic status, or manufacturer of the immunosuppressive drug(s) or limit an eligible attributed patients' choice of pharmacy when providing Part B and Part D immunosuppressive drug cost sharing support. In addition, IOTA participant must not accept financial or operational support for the Part B and Part D immunosuppressive drug cost sharing support from pharmacies and pharmaceutical manufacturers. Immunosuppressive drug regimens are adjusted to an individual's unique clinical characteristics to achieve a balance between preserving the health of the transplanted organ and reducing morbidity associated with long-term immunosuppression. We do not believe that the anti-kickback statute safe harbor for CMS-sponsored model patient incentives should be used to protect arrangements that could limit or influence attributed patients' access to the most clinically appropriate immunosuppressive drugs. Finally, to facilitate compliance monitoring, we are proposing that IOTA participants must maintain documentation regarding this beneficiary incentive. At minimum, the IOTA participant must maintain contemporaneous documentation that includes the identity of the eligible attributed patient to whom Part B and Part D immunosuppressive drug cost sharing support was provided, the date or dates on which Part B and Part D immunosuppressive drug cost sharing support was provided, and the amount or amounts of Part B and Part D immunosuppressive drug cost sharing support that was provided. IOTA participants must retain and provide access to the required documentation consistent with section III.C.12 of this proposed rule and § 1001.952(ii)(2).

We considered alternative safeguards for the Part B and Part D immunosuppressive drug cost sharing support policy. We considered requiring that an IOTA participant that wishes to offer Part B and Part D immunosuppressive drug cost sharing support must offer it to every attributed patient whose immunosuppressive drugs are covered by Part B or Part D and who does not have secondary insurance. Ultimately, we believe such a policy would run counter to our intention to offer IOTA participants flexibility to meet the needs of their attributed patient populations.

We also considered alternatives to the entirety of the proposed Part B and Part D immunosuppressive cost sharing support policy. We considered waiving Medicare payment requirements such that CMS would pay the full amount of the Part B or Part B–ID coinsurance for immunosuppressive drugs that are medically necessary for preventing or treating the rejection of a transplanted organ or tissue. If we were to pay 100 percent of the cost of immunosuppressive drugs for attributed patients who are Medicare beneficiaries whose immunosuppressive drugs are covered by Part B and attributed patients whose immunosuppressive drugs are covered by the Part B–ID

benefit, such attributed patients would have no cost sharing obligation. However, we believed that this policy would represent too large an impact to the IOTA Model savings estimates, and thus would potentially jeopardize our ability to continue to test the IOTA Model, if such a policy were finalized.

We also considered waiving the premium for the Part B–ID benefit. Under section 402(d) of the CAA and the implementing regulations at 42 CFR part 407 subpart D 408.20(f), the Secretary determines and promulgates a monthly premium rate for individuals enrolled in the Part B–ID benefit that is 15 percent of the monthly actuarial rate for beneficiaries who are age 65 and older. The Part B premium for 2024 for individuals enrolled in the Part B–ID benefit who file individual or joint tax returns with a modified adjusted gross income of less than or equal to $103,000 or $206,000 respectively, is $103.00. The Part B–ID premium is subject to income-related adjustments based on modified adjusted gross income. We believe the Part B–ID benefit monthly premium may represent a substantial out-of-pocket expenditure for individuals enrolled in the benefit given that it is prudent for the individual to acquire additional health insurance to cover other necessary health care services outside of immunosuppressive drugs. A premium waiver for the Part B–ID benefit is authorized by section 1115A(d)(1) of the Act, under which the Secretary may waive provisions of Title XVIII of the Act, including provisions of section 1836(b) of the Act, as may be necessary solely for purposes of carrying out section 1115A of the Act. We believe, however, that waiving the premium for the Part B–ID benefit would have too significant an impact on the IOTA Model savings estimates; therefore, we are not proposing to waive it for purposes of the IOTA Model.

We seek feedback on the proposal to allow an IOTA participant to subsidize the 20 percent coinsurance on immunosuppressive drugs covered by Part B or the Part B–ID benefit and the cost sharing associated with immunosuppressive drugs covered by Part D, when an attributed patient is eligible, meaning the attributed patient does not have secondary insurance and meets the eligibility criteria defined by the IOTA participant and approved by CMS prior to the PY in which the cost sharing support is provided. We are also soliciting input from interested parties on additional patient-centered safeguards that we may consider to protect cost sharing subsidies made under the proposed Part B and Part D immunosuppressive drug cost sharing support policy, if finalized.

(2) Attributed Patient Engagement Incentives

We believe that providing additional flexibilities under the IOTA Model would allow IOTA participants to support attributed patients in overcoming challenges associated with remaining active on the kidney transplant waitlist and adhering to comprehensive post-transplant care. Thus, we propose that IOTA participants may offer the following attributed patient engagement incentives under certain circumstances:

- Communication devices and related communication services directly pertaining to communication with an IOTA participant or IOTA collaborator to improve communication between an attributed patient and an IOTA participant or IOTA collaborator;
- Transportation to and from a transplant hospital that is an IOTA participant and between other providers and suppliers involved in the provision of ESRD care;
- Mental health services to address an attributed patient's behavioral health symptoms pre- and post-transplant; and
- In-home care to support the health of the attributed patient or the kidney transplant in the post-transplant period.

For the purposes of the proposed attributed patient engagement incentives, we are defining post-transplant period to mean the 90-day period following an attributed patient's receipt of a kidney transplant. We are proposing a 90-day post-transplant period because it may take up to 3 months for many individuals to fully recover from a kidney transplant.[304] We are proposing that attributed patient engagement incentives that are communication devices and related communication services, transportation to and from an IOTA participant and between other providers and suppliers involved in the provision of ESRD care, and mental health services to address an attributed patient's behavioral health symptoms could, under certain circumstances described in this section, be offered while an attributed patient is on a waitlist, after an attributed patient receives a transplant, or both. In-home care to support the health of the attributed patient or the kidney transplant may only be offered in the post-transplant period.

A mixed methods study of transplant providers' assessment of barriers to accessing a kidney transplant found that transportation was the most reported impediment to transplant.[305] Interested parties have informed us that transportation to medical appointments pre- and post-transplant, as well as to and from the dialysis center for treatments pre-transplant, is an important factor in maintaining active status on the list and the health of an individual and the graft after the transplant. Interested parties have also communicated with us about the importance of communication with waitlisted patients. We understand it can be common for an individual to not receive important information about the kidney transplant process when transplant hospitals and dialysis facilities do not communicate with one another about a patient's status. We believe we may be able to overcome this challenge by providing IOTA participants with greater flexibility to communicate directly with attributed patients about their status in the kidney transplant process.[306] [307] We understand that attributed patients who face communication and transportation barriers while on the kidney transplant waitlist may be inactivated, meaning that the attributed patient cannot receive organ offers. An attributed patient that cannot receive organ offers is misaligned with the IOTA Model's proposed performance assessment methodology, which would encourage an IOTA participant to increase its number of transplants. An attributed patient that cannot receive organ offers represents a missed opportunity for transplant, which is inconsistent with the goals of the proposed IOTA Model. Accordingly, we are interested in providing a framework under which an IOTA participant would be able to offer attributed patient engagement incentives in the form of communication devices and related communication services may increase the number of attributed patients who achieve and maintain active status on

[304] *Recovery after transplant surgery | American Kidney Fund.* (2021, December 14). *Www.kidneyfund.org. https://www.kidneyfund.org/kidney-donation-and-transplant/life-after-transplant-rejection-prevention-and-healthy-tips/recovery-after-transplant-surgery.*

[305] Browne, T., McPherson, L., Retzloff, S., Darius, A., Wilk, A.S., Cruz, A., Wright, S., Pastan, S.O., Gander, J.C., Berlin, A.A., & Patzer, R.E. (2021). Improving access to kidney transplantation: Perspectives from Dialysis and Transplant Staff in the Southeastern United States. Kidney Medicine, 3(5). *https://doi.org/10.1016/j.xkme.2021.04.017.*

[306] *Ibid.*

[307] Gillespie, A. (2021). Communication breakdown: Improving communication between transplant centers and dialysis facilities to improve access to kidney transplantation. Kidney Medicine, 3(5), 696–698. *https://doi.org/10.1016/j.xkme.2021.08.003.*

the kidney transplant waitlist. We believe the availability of transportation to and from an IOTA participant and between other providers and suppliers involved in the provision of ESRD care and mental health services to address an attributed patient's behavioral health symptom may also act in service of assisting more attributed patients in overcoming barriers to achieving or maintaining active status on a waitlist, among other challenges in the kidney transplant process prior to and after receiving a kidney transplant.

For example, we are also interested in providing greater flexibility to IOTA participants to support improved adherence to processes of care pre- and post-transplant that may support the ability of an attributed patient to accept an organ offer and the outcomes of the attributed patient and the graft after receiving a kidney transplant. Anxiety and depression may increase as attributed patients spend time on the kidney transplant waitlist.[308] Prevalence of depression is reported to decrease after kidney transplant, but may still exceed 20 percent.[309] Interested parties have reported that behavioral health symptoms interfere with adherence to care recommendations, including activities that support remaining active on the transplant waitlist and behaviors that support positive clinical outcomes for the patient and the graft after the kidney transplant procedure. Interested parties have also informed us of the importance of a transplant recipient having the support of another person in the home for a short period in the post-transplant period to enhance recovery.

We also believe providing the option for flexibility to offer attributed patient engagement incentives under the auspices of the IOTA Model would allow IOTA participants to provide attributed patients with tools to overcome barriers in the process of receiving a kidney transplant, thereby increasing adherence to the kidney transplant process, improving post-transplant outcomes, and supporting patient-centricity in the IOTA Model. As stated in section III.C.11.i. of this proposed rule, we expect to make the determination that the anti-kickback statute safe harbor for CMS-sponsored model patient incentives (§ 1001.952(ii)(2)) is available to protect the attributed patient engagement incentives proposed in this section when the incentives are offered or given to the attributed patient solely when the remuneration is exchanged between an IOTA participant and an attributed patient in compliance with this proposed rule and the conditions of the safe harbor for CMS-sponsored model patient incentives.

We are proposing programmatic requirements for the attributed patient engagement incentives. First, an IOTA participant must provide a written policy in a form and manner determined by CMS for the provision of attributed patient engagement incentives. The IOTA participant's written policy must be approved by CMS before the PY in which an attributed patient engagement incentive is first made available, and must be revalidated by CMS, in a form and manner specified by CMS, prior to each PY in which an IOTA participant wishes to offer an attributed patient engagement incentive subsequently. The IOTA participant's written policy must describe the items or services the IOTA participant plans to provide, an explanation of how each item or service that would be an attributed patient engagement incentive has a reasonable connection to, at minimum, one of the following: (1) achieving or maintaining active status on a kidney transplant waitlist; (2) accessing the kidney transplant procedure; or (3) the health of the attributed patient or the kidney transplant in the post-transplant period, and a justification for the need for the attributed patient engagement incentives that is specific to the IOTA participant's attributed patient population. The IOTA participant's written policy must also include an attestation that items that are attributed patient engagement incentives would be provided directly to an attributed patient, meaning that third parties would be precluded from providing an item that is an attributed patient engagement incentive to an attributed patient. We are not requiring an IOTA participant to provide any such attestation pertaining to services that are attributed patient engagement incentives because we acknowledge that services such as communication services, mental health services and in-home care services are generally provided by third parties. The IOTA participant would, however, be required to attest in its written policy that the IOTA participant would pay the service provider directly for services. Finally, the IOTA participant's written policy must also include an attestation that any items or services acquired by the IOTA participant that would be furnished as attributed patient engagement incentives would be acquired for the minimum amount necessary to for an attributed patient to achieve or maintain active status on the waitlist, access the kidney transplant procedure, or support the health of the attributed patient or the kidney transplant in the post-transplant period.

We are proposing the following restrictions on the provision of attributed patient engagement incentives. An IOTA participant must include in the written policy approved by CMS prior to offering an attributed patient engagement incentive, items that are attributed patient engagement incentives must be provided directly to an attributed patient and an IOTA participant must pay a service provider directly for any services that are offered as attributed patient engagement incentives. An IOTA participant must not offer attributed patient engagement incentives that are tied to the receipt of items of services from a particular provider or supplier or advertise or promote items or services that are attributed patient engagement incentives, except to make an attributed patient aware of the availability of the items or services at the time an attributed patient could reasonably benefit from them. An IOTA participant must not receive donations directly or indirectly to purchase attributed patient engagement incentives. Finally, items that are attributed patient engagement incentives must be retrieved from the attributed patient when the attributed patient is no longer eligible for that item or at the conclusion of the IOTA Model, whichever is earlier. Documented, diligent, good faith attempts to retrieve items that are attributed patient engagement incentives are deemed to meet the retrieval requirement.

We are proposing the following, additional restrictions pertaining to attributed patient engagement incentives that are communication devices, because we believe that such items may be especially susceptible to abuse. An IOTA participant's purchase of items that are communication devices must not exceed $1000 in retail value for any one attributed patient in any one PY. Items that are communication devices must remain the property of the IOTA participant. An IOTA participant must retrieve the item that is a communication device either when the attributed patient is no longer eligible for the communication device or at the conclusion of the IOTA Model,

[308] Corruble, E., Durrbach, A., Charpentier, B., Lang, P., Amidi, S., Dezamis, A., Barry, C., & Falissard, B. (2010). Progressive increase of anxiety and depression in patients waiting for a kidney transplantation. Behavioral Medicine, 36(1), 32–36. *https://doi.org/10.1080/08964280903521339.*

[309] Szeifert, L., Molnar, M.Z., Ambrus, C., Koczy, A.B., Kovacs, A.Z., Vamos, E.P., Keszei, A., Mucsi, I., & Novak, M. (2010). Symptoms of depression in kidney transplant recipients: A cross-sectional study. American Journal of Kidney Diseases, 55(1), 132–140. *https://doi.org/10.1053/j.ajkd.2009.09.022.*

whichever is earlier. Items that are communication devices must be retrieved from an attributed patient before another communication device may be provided to the same attributed patient. This restriction applies across PYs. In other words, an IOTA participant may not offer another communication device to the same attributed patient across all IOTA model years until the first communication device has been retrieved. We believe these additional restrictions on communication devices that are offered under the attributed patient engagement incentive policy are necessary to ensure that IOTA participants are not providing communication devices for purposes that are not aligned with the goals of the IOTA Model.

We are also proposing documentation requirements that pertain to the provision of attributed patient engagement incentives. The IOTA participant must maintain contemporaneous documentation of items and services furnished as attributed patient engagement incentives that includes, at minimum, the date an attributed patient engagement incentive is provided and the identity of the attributed patient to whom the item or service was provided. In accordance with the retrieval requirements for items that attributed patient engagement incentives, IOTA participants must document all retrieval attempts of items that are attributed patient engagement incentives, including the ultimate date of retrieval. IOTA participants must retain all records pertaining to the furnishing of attributed patient engagement incentives and make those records available to the Federal Government in accordance with section III.C.12. of this proposed rule.

Taken together, we believe the safeguards described in this section are necessary to ensure that attributed patient engagement incentives offered by an IOTA participant are provided in compliance with the intent of the proposed policy and the anti-kickback statute safe harbor for CMS-sponsored model patient incentives (§ 1001.952(ii)(2)).

We considered not allowing IOTA participants to offer attributed patient engagement incentives for attributed patients in the IOTA Model, which would simplify the IOTA Model. Further, having no attributed patient engagement incentive policy would allow IOTA participants to direct available resources to the proposed Part B and Part D immunosuppressive drug cost sharing support policy described in section III.C.h.(2). of this proposed rule. We took these considerations into account; however, we believe allowing for the maximum amount of flexibility possible for IOTA participants to meet the needs of attributed patients that relate to accessing a kidney transplant is consistent with the model's goals. In addition, we were unable to find any literature to suggest that one type of item or service, for example, cost sharing subsidies under Part B and Part D immunosuppressive drug cost sharing, is of greater value to an individual waiting for a kidney transplant or having received a kidney transplant than another, for example, an attributed patient engagement incentive. We also considered including dental services as a service that may be offered as an attributed patient engagement incentive. Sources of oral infection must be resolved before an individual can receive a kidney transplant because post-transplant immunosuppression puts a kidney transplant recipient at greater risk for oral infections that can spread to the rest of the body.[310] We did not include dental services as an allowable attributed patient engagement incentive because we understand that sources of oral infection must be resolved before an individual can be waitlisted for a kidney transplant; in other words, prior to the ability of an individual to be attributed to the IOTA Model. We are interested in receiving comments on the extent to which dental issues emerge once an individual has been listed for a kidney transplant and whether we should consider dental services as an attributed patient engagement incentive under the auspices of the IOTA Model.

We are soliciting feedback on our proposal to allow IOTA participants to offer attributed patient engagement incentives in a manner that complies with the restrictions and safeguards in this section. We are further soliciting feedback on other barriers to remaining active on the kidney transplant waitlist, receiving organ offers, and adhering to pre- and post-transplant care that we may be able to address by expanding the attributed patient engagement incentives available to attributed patients through future rulemaking.

i. Fraud and Abuse Waiver and OIG Safe Harbor Authority

Under section 1115A(d)(1) of the Act, the Secretary may waive such requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii) of the Act, and certain provisions of section 1934 of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act.

For this model and consistent with the authority under section 1115A(d)(1) of the Act, the Secretary may consider issuing waivers of certain fraud and abuse provisions in sections 1128A, 1128B, and 1877 of the Act. No fraud or abuse waivers are being issued in this document; fraud and abuse waivers, if any, would be set forth in separately issued documentation. Any such waiver would apply solely to the IOTA Model and could differ in scope or design from waivers granted for other programs or models. Thus, notwithstanding any provision of this proposed rule, IOTA participants and IOTA collaborators must comply with all applicable laws and regulations, except as explicitly provided in any such separately documented waiver issued pursuant to section 1115A(d)(1) of the Act specifically for the IOTA Model.

In addition to or in lieu of a waiver of certain fraud and abuse provisions in sections 1128A and 1128B of the Act, CMS proposes to waive sections 1881(b) and 1833(a) and 1833(b) of the Act only to the extent necessary to make payments under the IOTA Model. CMS further expects to make a determination, if this rule is finalized, that the anti-kickback statute safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives (§ 1001.952(ii)(1) and (2)) is available to protect remuneration exchanged pursuant to certain financial arrangements and patient incentives that may be permitted under the final rule, if issued. Specifically, we expect to determine that the CMS-sponsored models safe harbor would be available to protect the following financial arrangements and incentives: the IOTA Model Sharing Arrangement's gainsharing payments and alignment payments, the Distribution Arrangement's distribution payments, the Part B and Part D immunosuppressive drug cost sharing support policy and attributed patient engagement incentives.

We considered not allowing use of the safe harbor provisions. However, we determined that use of the safe harbor would encourage the goals of the model. We believe that a successful model requires integration and coordination among IOTA participants and other health care providers and suppliers. We believe the use of the safe harbor would encourage and improve beneficiary experience of care and coordination of

[310] Kwak, E.-J., Kim, D.-J., Choi, Y., Joo, D.J., & Park, W. (2020). Importance of oral health and dental treatment in organ transplant recipients. International Dental Journal, 70(6), 477–481. *https://doi.org/10.1111/idj.12585.*

care among providers and suppliers. We also believe these safe harbors offer flexibility for innovation and customization. The safe harbors allow for emerging arrangements that reflect up-to-date understandings in medicine, science, and technology.

We seek comment on this proposal, including that the anti-kickback safe harbor for CMS-sponsored model arrangements (§ 1001.952(ii)(1)) be available to IOTA participants and IOTA collaborators.

12. Audit Rights and Record Retention

By virtue of their participation in an Innovation Center model, IOTA participants and IOTA collaborators may receive model-specific payments, access to Medicare payment waivers, or some other model-specific flexibility, such as the ability to provide cost sharing support to eligible attributed patients for the proposed Part B and Part D immunosuppressive drug cost sharing support policy. It is therefore necessary and appropriate for CMS to audit, inspect, investigate, and evaluate records and other materials related to participation in the IOTA Model. CMS must be able to audit, inspect, investigate, and evaluate records and materials related to participation in the IOTA Model to allow us to ensure that IOTA participants are in no way denying or limiting the coverage or provision of benefits for beneficiaries as part of their participation in the IOTA Model. We propose to define ''model-specific payment'' to mean a payment made by CMS only to IOTA participants, or a payment adjustment made only to payments made to IOTA participants, under the terms of the IOTA Model that is not applicable to any other providers or suppliers; the term ''model-specific payment'' would include, unless otherwise specified, the model upside risk payment and downside risk payment, described in section III.C.6 of this proposed rule. It is necessary to propose this definition to distinguish payments and payment adjustments applicable to IOTA participants as part of their participation in the IOTA Model, from payments and payment adjustments applicable to IOTA participants as well as other providers and suppliers, as certain provisions of proposed part 512 would apply only to the former category of payments and payment adjustments.

There are audit and record retention requirements under the Medicare Shared Savings Program (see 42 CFR 425.314) and in other models being tested under section 1115A of the Act (see, for example, 42 CFR 510.110 and § 512.135).

We are proposing to adopt audit and record retention requirements for the IOTA Model. Specifically, as a result of our proposal to revise the scope of the general provisions of 42 CFR Part 512 Subpart A to include the IOTA Model, see proposed 42 CFR 512.100, we are proposing to apply § 512.135(a) through (c) to each IOTA participant and its IOTA collaborators. In applying § 512.135(a) to the IOTA Model, the Federal Government, including, but not limited to, CMS, HHS, and the Comptroller General, or their designees, would have a right to audit, inspect, investigate, and evaluate any documents and other evidence regarding implementation of an Innovation Center model. In applying existing § 512.135(b) and (c) to the IOTA model, an IOTA participant and its IOTA collaborators would be required to:

- Maintain and give the Federal Government, including, but not limited to, CMS, HHS, and the Comptroller General, or their designees, access to all documents (including books, contracts, and records) and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the IOTA Model, including, without limitation, documents and other evidence regarding all of the following:
  - ++ Compliance by the IOTA participant and its IOTA collaborators with the terms of the IOTA Model, including proposed new subpart A of proposed part 512.
  - ++ The accuracy of model-specific payments made under the IOTA Model.
  - ++ The IOTA participant's downside risk payments owed to CMS under the IOTA Model.
  - ++ Quality measure information and the quality of services performed under the terms of the IOTA Model, including proposed new subpart A of proposed part 512.
  - ++ Utilization of items and services furnished under the IOTA Model.
  - ++ The ability of the IOTA participant to bear the risk of potential losses and to repay any losses to CMS, as applicable.
  - ++ Where cost sharing support is furnished under the Part B and Part D immunosuppressive drug cost sharing support policy, the IOTA participant must maintain contemporaneous documentation that includes the identity of the eligible attributed patient to whom Part B and Part D immunosuppressive drug cost sharing support was provided, the date or dates on which Part B and Part D immunosuppressive drug cost sharing support was provided, and the amount or amounts of Part B and Part D immunosuppressive drug cost sharing support that was provided.
  - ++ Contemporaneous documentation of items and services furnished as attributed patient engagement incentives in accordance with § 512.458 that includes, at minimum, the date the attributed patient engagement incentive is provided and the identity of the attributed patient to whom the item or service was provided.
  - ++ Patient safety.
  - ++ Any other program integrity issues.
- Maintain the documents and other evidence for a period of 6 years from the last payment determination for the IOTA participant under the IOTA Model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—
  - ++ CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the IOTA participant at least 30 days before the normal disposition date; or
  - ++ There has been a termination, dispute, or allegation of fraud or similar fault against the IOTA participant or its IOTA collaborators, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

If CMS notifies the IOTA participant of a special need to retain a record or group of records at least 30 days before the normal disposition date, the IOTA participant would be required to maintain the records for such period of time determined by CMS. If CMS notifies the IOTA participant of a special need to retain records or there has been a termination, dispute, or allegation of fraud or similar fault against the IOTA participant or its IOTA collaborators, the IOTA participant would be required to notify its IOTA collaborators of the need to retain records for the additional period specified by CMS. This provision would ensure that that the government has access to the records.

We note that we previously adopted a rule at 42 CFR 512.110 defining the term ''days,'' as used in 42 CFR 512.135, to mean calendar days.

We invite public comment on these proposed provisions regarding audits and record retention.

13. Monitoring

a. General

We propose that CMS, or its approved designees, would conduct compliance

monitoring activities to ensure compliance by the IOTA participant and IOTA collaborators with the terms of the IOTA Model, including to understand IOTA participants' use of model-specific payments and to promote the safety of attributed patients and the integrity of the IOTA Model. Such monitoring activities would include, but not be limited to—

- Documentation requests sent to the IOTA participant and its IOTA collaborators, including surveys and questionnaires;
- Audits of claims data, quality measures, medical records, and other data from the IOTA participant and its IOTA collaborators;
- Interviews with the IOTA participant, including leadership personnel, medical staff, other associates and its IOTA collaborators;
- Interviews with attributed patients and their caregivers;
- Site visits to the IOTA participant, which would be performed in accordance with § 512.462, described below in section b of this proposed rule;
- Monitoring quality outcomes and attributed patient data;
- Tracking beneficiary complaints and appeals;
- Monitor the definition of and justification for the subpopulation of the IOTA participant's eligible attributed patients that may receive Part B and Part D Immunosuppressive Drug Cost Sharing Support in accordance with § 512.456; and
- Monitor the provision of attributed patient engagement incentives provided in accordance with § 512.458.

Additionally, CMS is concerned about IOTA participants bypassing the match run, as defined in section III.C.5.d.(1).(a). of this proposed rule, the rank order list of transplant candidates to be offered an organ. This practice, known as ''list diving,'' can improve efficiency in placing organs, but may undermine the mechanisms promoting fairness in rationing this scarce resource, if overused. We propose that CMS would monitor out of sequence allocation of kidneys by assessing how often top-ranked attributed patients receive the organ that was offered to them and if they did not receive it, what the reason for that was.

We believe these specific monitoring activities, which align with those currently used in other models being tested by the Innovation Center, are necessary to ensure compliance with the terms of the IOTA Model and can protect attributed patients from potential harm that may result from the activities of the IOTA participant or its IOTA collaborators, such as attempts to reduce access to or the provision of medically necessary covered services.

We propose that when CMS is conducting compliance monitoring and oversight activities, CMS or its designees would be authorized to use any relevant data or information, including without limitation Medicare claims submitted for items or services furnished to attributed patients who are Medicare beneficiaries. We believe that it is necessary to have all relevant information available to CMS during compliance monitoring and oversight activities, including any information already available to CMS through the Medicare program.

IOTA participants would remain subject to all existing requirements and conditions for Medicare participation as set out in Federal statutes and regulations and provider and supplier agreements, unless waived under the authority of section 1115A(d)(1) of the Act solely for purposes of testing the IOTA Model.

We seek feedback on how CMS should implement this monitoring proposal and any additional concerns regarding the overall monitoring approach.

b. Site Visits

We propose that IOTA participants would be required to cooperate in periodic site visits conducted by CMS or its designee. Such site visits would be conducted to facilitate the model evaluation performed pursuant to section 1115A(b)(4) of the Act and to monitor compliance with the IOTA Model requirements. We further propose that CMS or its designee would provide the IOTA participant with no less than 15 days advance notice of a site visit, to the extent practicable. Furthermore, we propose that, to the extent practicable, CMS would attempt to accommodate a request that a site visit be conducted on a particular date, but that the IOTA participant would be prohibited from requesting a date that was more than 60 days after the date of the initial site visit notice from CMS. We believe the 60-day period would reasonably accommodate IOTA participant schedules while not interfering with the operation of the IOTA Model. Further, we propose to require the IOTA participant to ensure that personnel with the appropriate responsibilities and knowledge pertaining to the purpose of the site visit be available during any and all site visits. We believe this proposal is necessary to ensure an effective site visit and prevent the need for unnecessary follow-up site visits.

Further, we propose that nothing in the previous sections would limit CMS from performing other site visits as allowed or required by applicable law. We believe that CMS must retain the ability to timely investigate concerns related to the health or safety of attributed patients or program integrity issues, and to perform functions required or authorized by law. In particular, we believe that it is necessary for CMS to monitor, and for IOTA participants to be compliant with our monitoring efforts, to ensure that they are not denying or limiting the coverage or provision of medically necessary covered services to attributed patients in an attempt to change model results or their model-specific payments, including discrimination in the provision of services to at-risk patients (for example, due to eligibility for Medicare based on disability).

In the alternative, we considered allowing unannounced site visits for any reason. However, we determined that giving advanced notice for site visits for routine monitoring would allow the IOTA participant to ensure that the personnel with the applicable knowledge is available and would allow the IOTA participant the flexibility to arrange these site visits around their operations. However, we propose that if there is a concern regarding issues that may pose risks to the health or safety of attributed patients or to the integrity of the IOTA Model, unannounced site visits would be warranted. We believe this would allow us to address any potential concerns in a timely manner without a delay that may increase those potential risks.

c. Reopening of Payment Determinations

To protect the financial integrity of the IOTA Model, we propose in § 512.462(d) that if CMS discovers that it has made or received a request from the IOTA participant about an incorrect model payment, CMS may make payment to, or demand payment from, the IOTA participant.

CMS' interests include ensuring the integrity and sustainability of the IOTA Model and the underlying Medicare program, from both a financial and policy perspective, as well as protecting the rights and interests of Medicare beneficiaries. For these reasons, CMS or its designee needs the ability to monitor IOTA participants to assess compliance with model terms and with other applicable Medicare program laws and policies. We believe our monitoring efforts help ensure that IOTA participants are furnishing medically necessary covered services and are not

falsifying data, increasing program costs, or taking other actions that compromise the integrity of the IOTA Model or are not in the best interests of the IOTA Model, the Medicare program, or Medicare beneficiaries.

We invite public comment on these proposed provisions regarding monitoring of the IOTA Model and alternatives considered.

14. Evaluation

Section 1115A(b)(4) of the Act requires the Secretary to evaluate each model tested under the authority of section 1115A of the Act and to publicly report the evaluation results in a timely manner. The evaluation must include an analysis of the quality of care furnished under the model and the changes in program spending that occurred due to the model. Models tested by the Innovation Center are rigorously evaluated. For example, when evaluating models tested under section 1115A of the Act, we require the production of information that is representative of a wide and diverse group of model participants and includes data regarding potential unintended or undesirable effects. The Secretary must take the evaluation into account if making any determinations regarding the expansion of a model under section 1115A(c) of the Act. In addition to model evaluations, the CMS Innovation Center regularly monitors model participants for compliance with model requirements.

For the reasons described in section III.C.11. of this proposed rule, these compliance monitoring activities are an important and necessary part of the model test. Therefore, we note that IOTA participants and their IOTA collaborators must comply with the requirements of 42 CFR 403.1110(b) (regarding the obligation of entities participating in the testing of a model under section 1115A of the Act to report information necessary to monitor and evaluate the model), and must otherwise cooperate with CMS' model evaluation and monitoring activities as may be necessary to enable CMS to evaluate the Innovation Center model in accordance with section 1115A(b)(4) of the Act. This participation in the evaluation may include, but is not limited to, responding to surveys and participating in focus groups.

15. Learning

In the Specialty Care Models final rule (85 FR 61114), we established the voluntary ETC Learning Collaborative (ETCLC). The goals of the ETCLC are to increase the supply and use of deceased donor kidneys by convening OPOs, transplant hospitals, donor hospitals, and patients and families to reduce the variation in OPO and transplant hospital performance and reduce kidney non-use.[311] The ETCLC is addressing three national aims over a 5-year period: (1) achieve a 28 percent absolute increase in the number of deceased donor kidneys with a KDPI greater than or equal to 60 recovered for transplant from the 2021 OPTN/SRTR baseline of 11,284; (2) decrease the current national non-use rate of all procured kidneys with a KDPI ≥60 by 20 percent; and (3) decrease the current national discard rate of all procured kidneys with a KDPI <60 by 4 percent. The ETCLC has developed Quality Improvement (QI) Teams that are identifying and implementing best practices based on the ETCLC Kidney Donation and Utilization Change Package. As of June 2023, 54 OPOs and 181 transplant hospitals were enrolled in ETCLC.[312]

While we considered continuing the ETCLC under the auspices of the IOTA Model, we are proposing to conclude the ETCLC at the end of the ETC Model test and implement a learning system specific to the IOTA Model. An IOTA Model learning system would deal only with issues specific to the IOTA Model and would have neither national aims nor include other providers in the transplant ecosystem such as OPOs or donor hospitals as regular participants. The advantages of this approach are that CMS could provide a forum for IOTA participants to discuss elements of the model, share experiences implementing IOTA Model provisions, and solicit support from peers in overcoming challenges that may arise. Since most transplant hospitals have less experience with Innovation Center models than other provider types, we believe an independent learning system would provide unique value to IOTA participants.

We also considered continuing ETCLC under the aegis of the IOTA Model. We believe many IOTA participants would already be enrolled in the ETCLC and dedicating staff and time to participating in QI Teams and engaging with the Kidney Donation and Utilization Change Package. We also believe that there may be overlap between the QI work being undertaken by ETCLC participants and the issues that would be of interest to IOTA participants. We further considered whether the ETCLC needs more time to achieve its national aims that could be provided by continuing the ETCLC under the IOTA Model.

We are soliciting feedback on our proposal to conclude the ETCLC with the ETC Model and implement a new learning system specific to the IOTA Model. We are also seeking feedback on the following questions:

- What are specific examples of how ETCLC is supporting transplant hospital QI to increase access to kidney transplant?
- What features of a new learning system would be important for IOTA participants?
- Could the ETCLC meet IOTA participants' need for QI support to succeed in the model?

16. Remedial Action and Termination

a. Remedial Action

We propose the Standard Provisions for Innovation Center Models relating to remedial actions, originally finalized as general provisions in the Code of Federal Regulations (42 CFR part 512 subpart A) that applied to specific Innovation Center models but that we are proposing for expansion to all Innovation Center Models with model performance periods that begin on or after January 1, 2025, in section II.B. of this proposed rule would apply to the IOTA Model. We propose that CMS could impose one or more remedial actions on the IOTA participant if CMS determines that—

- The IOTA participant has failed to furnish 11 or more transplants during the PY or any baseline years;
- The IOTA participant or its IOTA collaborator has failed to comply with any of the terms of the IOTA Model;
- The IOTA participant has failed to comply with transparency requirements as listed in section III.C.8.a. of this proposed rule;
- The IOTA participant or its IOTA collaborator has failed to comply with any applicable Medicare program requirement, rule, or regulation;
- The IOTA participant or its IOTA collaborator has taken any action that threatens the health or safety of an attributed patient;
- The IOTA participant or its IOTA collaborator has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the IOTA Model;
- The IOTA participant or its IOTA collaborator has undergone a Change in Control, as described in section III.C.17.b of this proposed rule, that presents a program integrity risk;

[311] *End Stage Renal Disease Treatment Choices Learning Collaborative—End Stage Renal Disease Treatment Choices Learning Collaborative—QualityNet Confluence.* (n.d.). *Qnetconfluence.cms.gov.* Retrieved May 30, 2023, from *https://qnetconfluence.cms.gov/display/ETCLC/End+Stage+Renal+Disease+Treatment+Choices+Learning+Collaborative.*

[312] Ibid.

• The IOTA participant or its IOTA collaborator is subject to any sanctions of an accrediting organization or a Federal, State, or local government agency;

• The IOTA participant or its IOTA collaborator is subject to investigation or action by HHS (including the HHS–OIG or CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint or filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the Federal Government has intervened, or similar action;

• The IOTA participant or its IOTA collaborator has failed to demonstrate improved performance following any remedial action imposed by CMS; or

• The IOTA participant has misused or disclosed the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the applicable data sharing agreement.

We propose that CMS may take one or more of the following remedial actions if CMS determines that one or more of the grounds for remedial action described in section III.C.16.a. of this proposed rule had taken place:

• Notify the IOTA participant and, if appropriate, require the IOTA participant to notify its IOTA collaborators of the violation;

• Require the IOTA participant to provide additional information to CMS or its designees;

• Subject the IOTA participant to additional monitoring, auditing, or both;

• Prohibit the IOTA participant from distributing model-specific payments, as applicable;

• Require the IOTA participant to terminate, immediately or by a deadline specified by CMS, its sharing arrangement with an IOTA collaborator with respect to the IOTA Model;

• Terminate the IOTA participant from the IOTA Model;

• Suspend or terminate the ability of the IOTA participant to provide cost sharing support for Part B and Part D immunosuppressive drugs, or attributed patient engagement incentives in accordance with III.C.11.h(1).

• Require the IOTA participant to submit a corrective action plan (CAP) in a form and manner and by a deadline specified by CMS;

• Discontinue the provision of data sharing and reports to the IOTA participant;

• Recoup model-specific payments;

• Reduce or eliminate a model specific payment otherwise owed to the IOTA participant, as applicable; or

• Such other action as may be permitted under the terms of the IOTA Model.

As part of the Innovation Center's monitoring and assessment of the impact of models tested under the authority of section 1115A of the Act, CMS has a special interest in ensuring that these model tests do not interfere with the program integrity interests of the Medicare program. For this reason, CMS monitors actions of IOTA participants for compliance with model terms, as well as other Medicare program rules. When CMS becomes aware of noncompliance with these requirements, it is necessary for CMS to have the ability to impose certain administrative remedial actions on a noncompliant model participant.

In the alternative, we considered a policy where the IOTA participant would remain in the IOTA Model regardless of any noncompliance. However, if there are circumstances in which the IOTA participant has engaged, or is engaged in, egregious actions, we are proposing that CMS may terminate the IOTA participant, as further described in section III.C.16.b. of this proposed rule. In addition, we considered allowing IOTA participants access to their data and reports regardless of their compliance with the requirements of the IOTA Model however we are proposing to discontinue data sharing and reports as a potential remedial action if there are grounds for doing so.

We seek comment on these proposed provisions regarding the proposed grounds for remedial actions, remedial actions generally, and whether additional types of remedial action would be appropriate.

b. Termination of IOTA Participant From the IOTA Model by CMS

We propose that CMS may immediately or with advance notice terminate an IOTA participant from participation in the IOTA Model if:

• CMS determines that it no longer has the funds to support the IOTA Model;

• CMS modifies or terminates the model pursuant to section 1115A(b)(3)(B) of the Act;

• CMS determines that the IOTA participant—

++ Has failed to comply with any model requirement or any other Medicare program requirement, rule, or regulation;

++ Has failed to comply with a monitoring or auditing plan or both;

++ Has failed to submit, obtain approval for, implement or fully comply with the terms of a CAP;

++ Has failed to demonstrate improved performance following any remedial action;

++ Has taken any action that threatens the health or safety of a Medicare beneficiary or other patient;

++ Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the IOTA Model; or

++ Assigns or purports to assign any of the rights or obligations under the model, voluntarily or involuntarily, whether by merger, consolidation, dissolution, operation of law, or any other manner, without the written consent of CMS;

• Poses significant program integrity risks, including but not limited to:

++ Is subject to sanctions or other actions of an accrediting organization or a Federal, State or local government agency; or

++ Is subject to investigation or action by HHS (including OIG or CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint, filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the government has intervened, or similar action.

We request comment and feedback on the proposal for termination of an IOTA participant from participating in the IOTA Model.

c. Termination of Model Participation by IOTA Participant

Given the mandatory nature of this model, we propose that an IOTA participant would not be able to terminate its own participation in the model. Maintaining a cohort of participants as close to 50 percent of eligible kidney transplant hospitals across the country is critical to evaluation of IOTA Model. As such, while we are proposing CMS may terminate an IOTA participant for reasons such as failure to meet eligibility criteria or change in kidney transplant hospital status, as described in section III.C.16.b. of this proposed rule, we are not proposing voluntary termination by the IOTA participant.

We considered allowing an IOTA participant to voluntarily terminate their participation in the model; however, we believe this went against the mandatory nature of the model and jeopardized our ability to evaluate model success and savings.

We solicit comment and feedback on our proposal not to allow IOTA participants to terminate their participation in the IOTA Model.

d. Financial Settlement Upon Termination

We propose that if CMS terminates the IOTA participant's participation in the IOTA Model or CMS terminates the IOTA Model, CMS would calculate the final performance score and any upside risk payment or downside risk payment, if applicable, for the entire PY in which the IOTA participant's participation in the model or the IOTA Model was terminated.

We propose that if CMS terminates an IOTA participant for any reason listed in section III.C.16.b of this proposed rule, CMS shall not make any payments of upside risk payment for the PY in which the IOTA participant was terminated and the IOTA participant shall remain liable for payment of any downside risk payment up to and including the PY in which termination becomes effective. We propose that CMS would determine the IOTA participant's effective date of termination.

We considered that in the event of termination, CMS would not pay any upside risk payments for the year in which the IOTA participant was terminated, but also only keep the IOTA participant liable for paying CMS any downside risk payments for completed PYs and not the year in which the IOTA participant is terminated. However, to deter poor or non-compliant performance, we believe it necessary to also keep the IOTA participant liable for paying to CMS any downside risk payment for the PY in which the IOTA participant is terminated.

We solicit comment on this proposal and alternative considered.

e. Termination of the IOTA Model

We are proposing that the general provisions relating to termination of the model by CMS in 42 CFR 512.165 would apply to the IOTA Model. Consistent with these provisions, in the event we terminate the IOTA Model, we would provide written notice to IOTA participants specifying the grounds for termination and the effective date of such termination or ending. As provided by section 1115A(d)(2) of the Act and § 512.170(e), termination of the model under section 1115A(b)(3)(B) of the Act would not be subject to administrative or judicial review. We propose that in the event of termination of the model, financial settlement terms would be the same as those proposed in section III.C.16.d. of this proposed rule.

17. Miscellaneous Provisions on Bankruptcy and Other Notifications

a. Notice of Bankruptcy

We propose that if an IOTA participant has filed a bankruptcy petition, whether voluntary or involuntary, the IOTA participant must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment has been made by either CMS or the IOTA participant under the terms of each model tested under section 1115A of the Act in which the IOTA participant is participating or has participated and all administrative or judicial review proceedings relating to any payments under such models have been fully and finally resolved. We propose the notice of bankruptcy must be sent by certified mail no later than 5 days after the petition has been filed and must contain a copy of the filed bankruptcy petition (including its docket number), and a list of all models tested under section 1115A of the Act in which the IOTA participant is participating or has participated. This list would not need to identify a model tested under section 1115A of the Act in which the IOTA participant participated if final payment has been made under the terms of the model and all administrative or judicial review proceedings regarding model-specific payments between the IOTA participant and CMS have been fully and finally resolved with respect to that model. The notice to CMS would be addressed to the CMS Office of Financial Management, Mailstop C3–01–24, 7500 Security Boulevard, Baltimore, Maryland 21244 or to such other address as may be specified on the CMS website for purposes of receiving such notices.

b. Change in Control

We propose that CMS could terminate an IOTA participant from the model if the IOTA participant undergoes a Change in Control. We propose that the IOTA participant shall provide written notice to CMS at least 90 days before the effective date of any Change in Control. For purposes of this rule, we propose a ''Change in Control'' would mean at least one of the following: (1) the acquisition by any ''person'' (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d–3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of the IOTA participant representing more than 50 percent of the IOTA participant's outstanding voting securities or rights to acquire such securities; (2) the acquisition of the IOTA participant by any individual or entity; (3) any merger, division, dissolution, or expansion of the IOTA participant (4) the sale, lease, exchange or other transfer (in one transaction or a series of transactions) of all or substantially all of the assets of the IOTA participant; or (5) the approval and completion of a plan of liquidation of the IOTA participant, or an agreement for the sale or liquidation of the IOTA participant.

c. Prohibition on Assignment

We propose that except with the prior written consent of CMS, an IOTA participant shall not transfer, including by merger (whether the IOTA participant is the surviving or disappearing entity), consolidation, dissolution, or otherwise: (1) any discretion granted it under the model; (2) any right that it has to satisfy a condition under the model; (3) any remedy that it has under the model; or (4) any obligation imposed on it under the model. We propose that the IOTA participant provide CMS 90 days advance written notice of any such proposed transfer. We propose this obligation remains in effect after the expiration or termination of the model or the IOTA participant's participation in the model and until final payment by the IOTA participant under the model has been made. We propose CMS may condition its consent to such transfer on full or partial reconciliation of upside risk payments and downside risk payments. We propose that any purported transfer in violation of this requirement is voidable at the discretion of CMS.

D. Requests for Information (RFIs) on Topics Relevant to the IOTA Model

This section includes several requests for information (RFIs). In responding to the RFIs, the public is encouraged to provide complete, but concise responses. These RFIs are issued solely for information and planning purposes; RFIs do not constitute a Request for Proposal (RFP), application, proposal abstract, or quotation. The RFIs do not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through these RFIs and would not accept unsolicited proposals. Respondents are advised that the U.S. Government would not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to these RFIs would be solely at the respondent's expense. Failing to

respond to any of the RFIs would not preclude participation in any future procurement, if conducted.

Please note that CMS would not respond to questions about the policy issues raised in these RFIs. CMS may or may not choose to contact individual respondents. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to these RFIs are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained because of this RFI may be used by the U.S. Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. All submissions become U.S. Government property and would not be returned. CMS may publicly post the comments received, or a summary thereof.

1. Patient-Reported Outcome Performance Measures (PRO–PM)

Chronic kidney disease is both complex and multifaceted and demands inclusive and thorough medical management, even after transplantation. Thus, when taking into consideration the lasting impact of CKD, symptom burden, and its correlation to mental health and psychosocial difficulties, it is important that the patient perspective and voice be included through the use of patient-reported outcome measures (PROMs) to truly grasp how CKD impacts their lives.[313]

Patient-reported measures are those measures where data comes directly from the patient. Broadly, patient-reported data includes patient-reported outcomes (PROs) and ePROs, which is the electronic capture of this data; patient-reported outcome measures (PROMs), which is the structure of how the PRO data is reported (for example, a survey instrument); and patient-reported outcome-based performance measures (PRO–PMs), which are reliable and valid quality measures of aggregated PRO data reported through a PROM and potentially used for performance assessment. PROMs include aspects pertaining health-related quality of life (HRQOL) and symptoms, both of which are essential measures in renal care. HRQOL can vary over time and course of an illness and these types of measures seek to examine the functioning and well-being in physical, mental, and social dimensions of life. It is also impacted by a variety of factors such as treatment, level of health, condition, culture, age, and psychosocial elements.[314]

Using PROMs or PRO–PMs are two ways to include the patient experience and has been acknowledged as a way for patients to provide critical insight about their symptoms, patient experience and quality of life.[315] In spite of the growing recognition over the past two decades that this is paramount to advancing the quality of care at both the patient and policy levels, there remains significant information gaps in understanding how PROMs are, and can be utilized across different domains, especially within nephrology to enrich patient-centered care, and measure other important quality components, such as access to transplantation, shared-decision making and quality of life post-transplantation, to provide a comprehensive understanding.[316]

In addition to the proposed measures the IOTA Model proposes would be used, as described in section III.C.5.e.(2) of this proposed rule, we would consider incorporating a measure of HRQOL and access to waitlist.

We seek comments on the inclusion of a HRQOL patient-reported outcome measure in the IOTA Model, as well as on the inclusion of an access to waitlist measure. We are seeking input to the questions later in this section, and comment on any aspect of a kidney transplant recipient patient experience measure that should be included in a new measure or existing and validated measurement tools and instruments appropriate for use in the IOTA Model.

- For a meaningful evaluation of transplant program outcomes from the recipient point of view, are there currently any validated PROMs of quality of life that are appropriate for use in the IOTA Model?
- Are there specific aspects of quality of life (QOL) that are particularly important to include for these populations? Why are these aspect(s) of QOL a high priority for inclusion in a survey? What should these metrics be (that is, measurement tools, instruments, concepts)? How should they be measured?
- For kidney transplant recipients: What other topic area(s) should be included in a new patient-reported outcome measure or performance measure assessing quality of life?
- For kidney transplant recipients: What domains of HRQOL can be influenced or improved by actions taken by transplant hospital and thus may be appropriate for performance measurement?

In addition, we are seeking input on the questions later in this section on

[313] Schick-Makaroff, K., Thummapol, O., Thompson, S., Flynn, R., Karimi-Dehkordi, M., Klarenbach, S., Sawatzky, R., & Greenhalgh, J. (2019). Strategies for incorporating patient-reported outcomes in the care of people with chronic kidney disease (PRO kidney): a protocol for a realist synthesis. *Systematic Reviews, 8*(1). *https://doi.org/10.1186/s13643-018-0911-6;* Brett, K.E., Ritchie, L.J., Ertel, E., Bennett, A., & Knoll, G.A. (2018). Quality Metrics in Solid Organ Transplantation. *Transplantation, 102*(7), e308–e330. *https://doi.org/10.1097/tp.0000000000002149;* Mendu, M.L., Tummalapalli, S.L., Lentine, K.L., Erickson, K.F., Lew, S.Q., Liu, F., Gould, E., Somers, M., Garimella, P.S., O'Neil, T., White, D.L., Meyer, R., Bieber, S.D., & Weiner, D.E. (2020). Measuring Quality in Kidney Care: An Evaluation of Existing Quality Metrics and Approach to Facilitating Improvements in Care Delivery. *Journal of the American Society of Nephrology, 31*(3), 602–614. *https://doi.org/10.1681/ASN.2019090869;* Tang, E., Bansal, A., Novak, M., & Mucsi, I. (2018). Patient-Reported Outcomes in Patients with Chronic Kidney Disease and Kidney Transplant—Part 1. *Frontiers in Medicine, 4. https://doi.org/10.3389/fmed.2017.00254;* Anderson, N.E., Calvert, M., Cockwell, P., Dutton, M., Aiyegbusi, O.L., & Kyte, D. (2018). Using patient-reported outcome measures (PROMs) to promote quality of care in the management of patients with established kidney disease requiring treatment with haemodialysis in the UK (PROM–HD): a qualitative study protocol. *BMJ Open, 8*(10), e021532. *https://doi.org/10.1136/bmjopen-2018-021532.*

[314] Pagels, A.A., Stendahl, M., & Evans, M. (2019). Patient-reported outcome measures as a new application in the Swedish Renal Registry: Health-related quality of life through Rand-36. *Clinical Kidney Journal, 13*(7), 442–449. *https://doi.org/10.1093/ckj/sfz084;* Broadbent, E., Petrie, K.J., Main, J., & Weinman, J. (2006). The Brief Illness Perception Questionnaire. *Journal of Psychosomatic Research, 60*(6), 631–637. *https://doi.org/10.1016/j.jpsychores.2005.10.020;* Mclaren, S., Jhamb, M., & Unruh, M. (2021). Using patient-reported measures to improve outcomes in kidney disease. *Blood Purification, 50*(4–5), 649–654. *https://doi.org/10.1159/000515640.*

[315] Schick-Makaroff, K., Thummapol, O., Thompson, S., Flynn, R., Karimi-Dehkordi, M., Klarenbach, S., Sawatzky, R., & Greenhalgh, J. (2019). Strategies for incorporating patient-reported outcomes in the care of people with chronic kidney disease (PRO kidney): a protocol for a realist synthesis. *Systematic Reviews, 8*(1). *https://doi.org/10.1186/s13643-018-0911-6;* Brett, K.E., Ritchie, L.J., Ertel, E., Bennett, A., & Knoll, G.A. (2018). Quality Metrics in Solid Organ Transplantation. *Transplantation, 102*(7), e308–e330. *https://doi.org/10.1097/tp.0000000000002149;* Mendu, M.L., Tummalapalli, S.L., Lentine, K.L., Erickson, K.F., Lew, S.Q., Liu, F., Gould, E., Somers, M., Garimella, P.S., O'Neil, T., White, D.L., Meyer, R., Bieber, S.D., & Weiner, D.E. (2020). Measuring Quality in Kidney Care: An Evaluation of Existing Quality Metrics and Approach to Facilitating Improvements in Care Delivery. *Journal of the American Society of Nephrology, 31*(3), 602–614. *https://doi.org/10.1681/ASN.2019090869;* Tang, E., Bansal, A., Novak, M., & Mucsi, I. (2018). Patient-Reported Outcomes in Patients with Chronic Kidney Disease and Kidney Transplant—Part 1. *Frontiers in Medicine, 4. https://doi.org/10.3389/fmed.2017.00254;* Anderson, N.E., Calvert, M., Cockwell, P., Dutton, M., Aiyegbusi, O.L., & Kyte, D. (2018). Using patient-reported outcome measures (PROMs) to promote quality of care in the management of patients with established kidney disease requiring treatment with haemodialysis in the UK (PROM–HD): a qualitative study protocol. *BMJ Open, 8*(10), e021532. *https://doi.org/10.1136/bmjopen-2018-021532.*

[316] Ibid.

existing PROMs and quality measures that are currently being used by transplant hospitals.

• Which patient-reported outcomes measure(s) that assess quality of life in kidney transplant recipients are currently being used?

++ What information is collected in these PROMs? How well do these surveys perform? What are the strengths of the survey(s) currently in use?

++ What content area(s) are missing from these survey(s) that are currently in use?

++ Which content area(s) are low priority or not useful in these currently used survey(s)? Why are they not useful?

++ How are the results and findings of these current survey(s) used to evaluate and improve quality of life/care? Are the results and findings of these current survey(s) used for other purposes?

• Are there any other PROMs or PRO–PMs that CMS should consider using to measure a transplant program's performance?

• Are there any other quality measures in general that CMS should consider using to measure a transplant program's performance?

• For transplant hospitals: Can PROs be effectively used to assess performance?

• For transplant hospitals: Does a reporting requirement effectively incentivize a transplant hospital to improve patient quality of life without tying payment to performance?

The integration and implementation of PROMs can be challenging for transplant hospitals as it requires additional resources (that is, appropriate infrastructure with regard to technological capability or data security), time, and there may be uncertainty about how to interpret and use the data to improve patient care.[317] We are also seeking information on implementation challenges and support.

• When is the appropriate time to measure HRQOL post-transplantation?

• For transplant hospitals: What, if any, challenge(s) are there to collecting information about patient quality of life?

• For kidney transplant recipients: What, if any, challenge(s) are there to reporting information about patient quality of life?

• For transplant hospitals: What actions or approaches by transplant hospitals would facilitate the collection of quality of life information?

++ What data collection approach(es) would be most likely to promote participation by transplant recipients to a survey (for example, web-based; paper-and-pencil; etc.)?

++ How much time would transplant hospitals need to build processes to collect and use data in a meaningful way?

• For transplant hospitals: How could CMS support transplant hospitals in introducing a measure like this into the model?

2. Access to Waitlist Measure

The kidney transplant waitlist is a list of individuals with ESRD who need a kidney transplant. To be placed on the wait list for a kidney transplant, individuals must be referred and then undergo a comprehensive evaluation process by a transplant center.

Organ transplantation and donation in the U.S. remains highly inequitable amongst racial and ethnic minorities as compared to White Americans, with many factors influencing disparities.[318] As one study notes regarding kidney transplants, ''racial disparities were observed in access to referral, transplant evaluation, waitlisting and organ receipt'' and ''SES [socioeconomic status] explained almost one-third of the lower rate of transplant among black versus white patients, but even after adjustment for demographic, clinical and SES factors, blacks had a 59 percent lower rate of transplant than whites.'' [319]

In addition, Black/African Americans, Hispanics/Latinos, Asian Americans, and other minorities are at a higher risk of illnesses that may eventually lead to kidney failure, such as diabetes and high blood pressure.[320] ''Black/African Americans are almost 4 times more likely and Hispanics or Latinos are 1.3 times more likely to have kidney failure as compared to White Americans.'' [321] Yet those Black/African American and Hispanic/Latinos patients on dialysis are less likely to be placed on the transplant waitlist and also have a lower likelihood of transplantation.[322] In particular, Black/African Americans make up the largest group of minorities in need of an organ transplant and yet the number of organ transplants performed on Black/African Americans in 2020 was 28.5 percent of the number of Black/African Americans currently waiting for a transplant.[323] The number of transplants performed on White Americans, however, was 40.4 percent of the number currently waiting.[324]

We are seeking public comments on the following questions:

• For kidney transplant hospitals: What existing measures are currently being used to measure access to the waitlist?

++ What are the strengths and weaknesses of those measures?

++ What are the domains of those measures?

• For kidney transplant recipients and dialysis and ESRD patients: Why is a quality measure that looks at access to waitlist important to include?

• When measuring access to waitlist, what components should be analyzed (for example, time from referral to waitlist, time from waitlist to transplant)?

• What data would be necessary to create a measure on those specified components? How could that data be transmitted to CMS that minimizes additional burden to transplant hospitals?

• What data would be necessary to create a measure of time to referral to waitlist, time from referral to waitlist and time from waitlist to transplant? How could that data be transmitted to CMS that reduces burden to transplant hospitals?

While we would not be responding to specific comments submitted in response to this RFI, we intend to use

[317] Ju, A., Cazzolli, R., Howell, M., Scholes-Robertson, N., Wong, G., & Jaure, A. (n.d.). Novel Endpoints in Solid Organ Transplantation: Targeting Patient-reported Outcome Measures. *Transplantation,* 10.1097/TP.0000000000004537. *https://doi.org/10.1097/TP.0000000000004537;* Aiyegbusi, O.L., Kyte, D., Cockwell, P., Anderson, N., & Calvert, M. (2017). A patient-centred approach to measuring quality in kidney care. *Current Opinion in Nephrology and Hypertension, 26*(6), 442–449. *https://doi.org/10.1097/mnh.0000000000000357;* MacLean, C.H., Antao, V.C., Fontana, M.A., Sandhu, H.S., & McLawhorn, A.S. (2021). PROMs: Opportunities, Challenges, and Unfinished Business. *NEJM Catalyst, 2*(11). *https://doi.org/10.1056/cat.21.0280.*

[318] *Inequity in Organ Donation · The Costly Effects of an Outdated Organ Donation System.* (n.d.). Bloomworks.digital. https://bloomworks.digital/organdonationreform/Inequity/; Patzer, R.E., Perryman, J.P., Schrager, J.D., Pastan, S., Amaral, S., Gazmararian, J.A., Klein, M., Kutner, N., & McClellan, W.M. (2012). The Role of Race and Poverty on Steps to Kidney Transplantation in the Southeastern United States. *American Journal of Transplantation, 12*(2), 358–368. *https://doi.org/10.1111/j.1600-6143.2011.03927.x.*

[319] Patzer, R.E., Perryman, J.P., Schrager, J.D., Pastan, S., Amaral, S., Gazmararian, J.A., Klein, M., Kutner, N., & McClellan, W.M. (2012). The Role of Race and Poverty on Steps to Kidney Transplantation in the Southeastern United States. *American Journal of Transplantation, 12*(2), 358–368. *https://doi.org/10.1111/j.1600-6143.2011.03927.x*

[320] National Kidney Foundation. (2016, January 7). *Minorities and kidney disease.* National Kidney Foundation. *https://www.kidney.org/atoz/content/minorities-KD.*

[321] Ibid.

[322] Reed, R.D., & Locke, J.E. (2019). Social Determinants of Health. *Transplantation,* 1. *https://doi.org/10.1097/tp.0000000000003003.*

[323] *Organ and Tissue Donation—The Office of Minority Health.* (2019). *Hhs.gov. https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=27.*

[324] Ibid.

this input to inform any future quality measure efforts.

3. Interoperability

Improved interoperability of software systems and tools used to manage CKD, ESRD, and kidney transplant patients supports the goals of value-based care to encourage care coordination and data-driven decision making to improve outcomes and lower healthcare expenditures. We understand that transplant hospitals rely on transplant specific platforms that are components of market-leading electronic health records (EHRs) or transplant management software that can integrate into an existing EHR. Dialysis organizations and dialysis facilities generally use hemodialysis-specific EHRs from large software companies.[325] EHRs have proprietary components that have historically limited the transfer of clinical data to other EHRs and clinical systems, though interest in exchange, defined at 45 CFR 171.102 as the ability for electronic health information to be transmitted between and among different technologies, systems, platforms, or networks, is growing.[326] Exchange is facilitated by health information networks or health information exchanges, defined at 45 CFR 171.102 as an individual or entity that determines, controls, or has the discretion to administer any requirement, policy, or agreement that permits, enables, or requires the use of any technology or services for access, exchange, or use of electronic health information among more than two unaffiliated individuals or entities (other than the individual or entity to which this definition might apply) that are enabled to exchange with each other; and that is for a treatment, payment, or health care operations purpose, as such terms are defined in 45 CFR 164.501 regardless of whether such individuals or entities are subject to the requirements of 45 CFR parts 160 and 164. For the purposes of this proposed rule, we refer to health information networks or health information exchanges, as defined at 45 CFR 171.102, solely as health information exchanges. Health information exchanges facilitate exchange via different mechanisms, such as within a proprietary EHR or across different geographic areas. For example, a transplant hospital may be connected to several local organizations, sometimes called regional health information organizations (RHIOs), that organize and facilitate exchange within a defined geographic area. Dialysis organizations are investing in exchange to streamline the transmission of clinical data and improve care coordination; for example, to support the management of patients across the transition of care between CKD and ESRD.[327]

Interest has also grown in the use of health information technology (HIT), defined at 45 CFR 170.102 as ''hardware, software, integrated technologies or related licenses, IP, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information.'' HIT can be leveraged to track transplant referrals, a patient's progress through transplant evaluation, pre-transplant testing results, and waitlist status.[328] HIT can also be used to communicate the status of a transplant referral and support care coordination by allowing for sharing of a patient's records between a dialysis facility and a transplant hospital.

Despite the growth of data exchange and investment in kidney and transplant care HIT, an infrastructure for interoperability that supports the exchange of clinical data across different HIT tools, different approaches to exchange, and proprietary systems and tools is still emerging. We understand that barriers to interoperability create silos that limit care coordination between transplant hospitals, as well as with dialysis facilities and nephrology practices.

Use of health information exchanges that facilitate data sharing across different platforms, tools and non-affiliated health care providers, referred to hereafter as non-proprietary health information exchanges (HIEs), may have special value to participants in value-based care models. For example, a central convener could facilitate data sharing to support care coordination among model participants that are supported by different EHR vendors.[329] Non-proprietary HIEs are particularly important for clinicians and health care organizations that do not use an EHR with a significant share of the market or who engage in broader co-management of their patient population.[330]

Implementation of non-proprietary exchange has been fragmented due to a patchwork of local, State, and Federal investments.[331] The Health Information Technology for Economic and Clinical Health Act (HITECH Act), part of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5), made grants to State-based organizations to provide the framework and governance for non-proprietary exchange, the only restriction being geography.[332] As a result, non-proprietary exchange can be regionally based. Non-proprietary exchange facilitated on a regional basis has geographic limitations, including that providers outside an RHIO's area of operation have little incentive to participate in a RHIO with other providers with which they do not share patients.[333] Overcoming regional barriers to exchange could be an important element of realizing the value of non-proprietary exchange in the IOTA Model and for value-based care efforts, more broadly.

The Trusted Exchange Framework and Common Agreement (TEFCA) is an initiative to facilitate exchange of electronic health information across health information networks. In the 21st Century Cures Act, Congress required the National Coordinator to convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally.[334] ONC released the Trusted Exchange Framework, Common Agreement—Version 1, and Qualified Health Information Network (QHIN) Technical Framework—Version 1, which appeared in the **Federal Register** on January 19, 2022 (87 FR 2800). Version 1.1 of the Common Agreement appeared in the **Federal Register** on November 7, 2023 (88 FR

[325] Sutton, P.R., & Payne, T.H. (2019). Interoperability of electronic health information and care of dialysis patients in the United States. *Clinical Journal of the American Society of Nephrology, 14(*10), 1536–1538. *https://doi.org/10.2215/cjn.05300419.*

[326] *HealthIt.gov.* (2019, April 18). *Health Information Exchange | HealthIT.gov. Healthit.gov. https://www.healthit.gov/topic/health-it-and-health-information-exchange-basics/health-information-exchange.*

[327] *Interoperability Reduces Provider Burden and Improves Patient Care.* (n.d.). *Fmcna.com.* Retrieved March 18, 2024, from *https://fmcna.com/insights/amr/2019/advancing-interoperability-to-reduce-provider-burden-and-improve/.*

[328] Wu, C., Shah, N., Sood, P., Chethan Puttarajappa, Bernardo, J.F., Mehta, R., Tevar, A. D., Shapiro, R., Tan, H.P., Wijkstrom, M., Sturdevant, M., & Hariharan, S. (2014). Use of the Electronic Health Record (EHR) to Improve the Pre-Transpalnt Process for Kidney and Pancreas Transplantation. *Transplantation, 98,* 833–834. *https://doi.org/10.1097/00007890-201407151-02846.*

[329] Everson, J., & Cross, D.A. (2019). Mind the gap: the potential of alternative health information exchange. *The American journal of managed care, 25.*(1), 32–38.

[330] *Ibid.*

[331] Holmgren, A.J., & Adler-Milstein, J. (2017). Health Information Exchange in US hospitals: The current landscape and a path to improved information sharing. Journal of Hospital Medicine, 12(3), 193–198. *https://doi.org/10.12788/jhm.2704.*

[332] Ibid.

[333] Ibid.

[334] Section 4003(b) of the 21st Century Cures Act (Pub. L. 114–255)

76773). ONC anticipates releasing Version 2 of the Common Agreement in 2024. Version 2 is anticipated to include updates that will support Health Level Seven (HL7®) Fast Healthcare Interoperability Resources (FHIR®) based transactions.[335]

TEFCA has three goals:

- Establish a governance, policy, and technical floor for nationwide interoperability;
- Simplify connectivity for organizations to securely exchange information to improve patient care, enhance the welfare of populations, and generate health care value; and
- Enable individuals to gather their health care information.[336]

TEFCA promotes interoperability by defining technical standards and a governing approach for secure information sharing on a national scale. The Recognized Coordinating Entity (RCE) develops, updates, implements, and maintains the Common Agreement. The RCE is also responsible for soliciting and reviewing applications from organizations seeking QHIN status, administering the QHIN designation, operationalizing the Common Agreement, overseeing Qualified Health Information Network (QHIN)-facilitated network operations, and monitoring compliance by participating QHINs.[337]

QHINs are health information networks that agree to the common terms and conditions of exchange with each other, as specified in the Common Agreement, and to the functional and technical requirements for exchange (as specified in the QHIN Technical Framework (QTF)). Each QHIN voluntarily enters into an agreement with the RCE by signing the Common Agreement. On February 13, 2023, HHS announced the first six applicant organizations approved for onboarding as QHINs under TEFCA.[338] On December 12, 2023, TEFCA became operational as five organizations that completed the TEFCA onboarding process were officially designated as QHINs.[339] On February 12, 2024, HHS announced the designation of two additional organizations as QHINs.[340]

CMS acknowledged the importance of TEFCA in the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation final rule (87 FR 48780) by adding Enabling Exchange under TEFCA (87 FR 49329) as a new measure under the Health Information Exchange Objective for the Medicare Promoting Interoperability Program. Participants in the Medicare Promoting Interoperability Program may also earn credit for the Health Information Exchange Objective by reporting on the previously finalized Health Information Exchange (HIE) Bidirectional Exchange measure (86 FR 45470).

In the Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs To Provide Refunds With Respect to Discarded Amounts; and COVID–19 Interim Final Rules final rule (87 FR 70067 through 70071), CMS also added a new optional measure, Enabling Exchange Under TEFCA, to the Health Information Exchange objective for the Merit-based Incentive Payment System (MIPS) Promoting Interoperability performance category beginning with the CY 2023 performance period/2025 MIPS payment year. Currently, for the CY 2024 performance period/2026 MIPS payment year, MIPS eligible clinicians may fulfill the Health Information Exchange objective via three avenues by reporting: (1) the two Support Electronic Referral Loops measures; (2) the Health Information Exchange Bidirectional Exchange measure; or (3) the Enabling Exchange under TEFCA measure (88 FR 79357 through 79362).

CMS would like to support IOTA participants' interoperability efforts that could lead to best practices in CKD and ESRD care. However, we recognize that given the existing Federal interoperability initiatives, we do not want to create duplicate efforts or create unnecessary burden on IOTA participants. We are seeking comment on how CMS can promote interoperability in the proposed IOTA model; in particular, we seek comment on the extent to which participants are planning on participating in TEFCA in the next 1–2 years, as well as other means by which interoperability may support care coordination in the IOTA model. Any further proposals related to interoperability included in the IOTA model would be proposed through future notice and comment rulemaking.

IV. Collection of Information Requirements

The Standard Provisions for Innovation Center Models and the Increasing Organ Transplant Access (IOTA) Model would be implemented and tested under the authority of the CMS Innovation Center. Section 1115A of the Act authorizes the CMS Innovation Center to test innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries while reducing program expenditures. As stated in section 1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of models under section 1115A of the Act. As a result, the information collection requirements contained in this proposed rule would need not be reviewed by the Office of Management and Budget.

V. Regulatory Impact Analysis

A. Statement of Need

The best treatment for most patients with kidney failure is transplantation. Kidney transplants provide improved survival and quality of life relative to dialysis and generates savings to the Medicare Trust Fund over 10 years, but only 30 percent of patients with end-stage renal disease (ESRD) are living with one.[341] The underutilization of kidney transplantation is particularly

[335] *Trusted Exchange Framework and Common Agreement (TEFCA) | HealthIT.gov.* (n.d.). *www.healthit.gov. https://www.healthit.gov/topic/interoperability/policy/trusted-exchange-framework-and-common-agreement-tefca.*

[336] *3 . . . 2 . . . 1 . . . TEFCA is Go for Launch.* (2022, January 18). Health IT Buzz. *https://www.healthit.gov/buzz-blog/interoperability/321tefca-is-go-for-launch.*

[337] *https://rce.sequoiaproject.org/.*

[338] *Building TEFCA.* (2023, February 13). Health IT Buzz. *https://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/interoperability-electronic-health-and-medical-records/building-tefca.*

[339] Affairs (ASPA), A. S. for P. (2023, December 12). *HHS Marks Major Milestone for Nationwide Health Data Exchange. www.hhs.gov. https://www.hhs.gov/about/news/2023/12/12/hhs-marks-major-milestone-nationwide-health-data-exchange.html.*

[340] *https://www.hhs.gov/about/news/2024/02/12/hhs-expands-tefca-by-adding-two-additional-qhins.html.*

[341] Organ Procurement and Transplantation Network. Kidney Donor Profile Index (KDPI) Guide for Clinicians. *https://optn.transplant.hrsa.gov/professionals/by-topic/guidance/kidney-donor-profile-index-kdpi-guide-for-clinicians/#:~:text=Figure%201%20shows%20that%20a,function%20for%20about%209%20years;* United States Renal Data System. 2022. USRDS Annual Report. Volume 2. End-stage Renal Disease (ESRD) in the United States, Chapter 9: Healthcare Expenditures for Persons with ESRD. Figure 9.11.

prominent among structurally disadvantaged populations. The kidney transplant process involves silos of care, gaps in accountability, disparities, and misaligned financial incentives that we believe value-based care incentives are well positioned to target.[342]

The proposed IOTA Model would be a mandatory payment model, beginning on January 1, 2025, and ending December 31, 2030, that tests whether upside and downside performance-based payments (''upside risk payments'' and ''downside risk payments'') increase the number of kidney transplants performed by select IOTA participants (that is, transplant hospitals). Performance would be measured across three domains: (1) Achievement; (2) Efficiency; and (3) Quality. The achievement domain would assess each selected IOTA participant on the overall number of kidney transplants performed relative to a participant-specific target. The efficiency domain would assess the kidney organ offer acceptance rates of each selected IOTA participant relative to a national rate. The quality domain would assess the quality of care provided by the selected IOTA participant across a set of outcome metrics and quality measures. Each selected IOTA participant's performance score across these three domains would determine the amount of the performance-based payment that CMS would pay to the selected IOTA participant, or that the selected IOTA participant would pay to CMS. The upside risk payment would be a lump sum payment paid by CMS to the selected IOTA participants with high final performance scores. Conversely, the downside risk payment would be a lump sum payment paid to CMS by the selected IOTA participants with low final performance scores.

1. Analytic Baseline

Historical data for the analytic baseline are from the Organ Procurement and Transplant Network/Scientific Registry of Transplant Recipients (OPTN/SRTR).[343] There were 24,667 total adult kidney transplants in the United States in 2021, with a growth rate of 7.3 percent from 2020 to 2021. Similarly, the 5-year compound annual growth rate (CAGR) for the pre-pandemic years of 2015–2019 was 7.1 percent. The majority, 86.7 percent, of adult kidney transplants were from deceased donors in 2021. The trend in growth for deceased donor kidney transplants has been steadily increasing since the revision of the kidney allocation system in 2014, while the trend in growth for living donor kidney transplants has been relatively stable. The number of adult deceased donor kidney transplants increased 5.7 percent from 2020 to 2021, a slowdown from the 2015–2019 CAGR of 7.8 percent.

Among the 18,931 adult deceased donor kidney transplant recipients in 2021, 64.7 percent reported Medicare as their primary payer (stable from 64.8 percent in 2020) and 24.0 percent reported private insurance as their primary payer (down from 25.7 percent in 2020). Deceased donor kidney transplant recipients had 2015–2019 CAGR of 6.9 percent for Medicare as their primary payer and 11.6 percent for private insurance as their primary payer. The age distribution of the 18,931 adult deceased donor kidney transplant recipients in 2021 showed that the majority of recipients are younger than the aged Medicare population. Specifically, 11.5 percent of recipients were ages 18–34 years, 26.1 percent were ages 35–49 years, 40.5 percent were ages 50–64 years, and 21.9 percent were at least 65 years of age at the time of transplant. The 2015–2019 CAGR was greatest for the two latter age categories, at 9.3 percent and 14.4 percent for ages 50–64 years and 65+ years, respectively.

The supply of donated kidneys has not grown with the demand from kidney transplant recipient candidates. There were a total of 96,130 adult kidney transplant candidates on the transplant waitlist at the end of the year in 2021, which included 41,765 newly added candidates. The number of newly added adult candidates to the waitlist increased 11.7 percent from 2020 to 2021, recovering from the pandemic-related decline in the prior year, and exceeding the 2015–2019 CAGR of 9.2 percent.

For the proposed model, we assumed an average of $40,000 in savings to Medicare over a 10-year period for each additional kidney transplant furnished to a Medicare beneficiary compared to remaining on dialysis. For the 50 percent of IOTA participants proposed to be randomly selected to participate in the model, we assume that the total number of kidney transplants from all payers over the 6-year model performance period would have a CAGR of 6.6 percent in the absence of the model (for example, if the rule is not finalized). We also assume that the 6-year model performance period CAGR for the total number of kidney transplants furnished to beneficiaries with Medicare as the primary payer would be 7.0 percent. The baseline share of deceased donor kidneys that are currently discarded is roughly 20 percent. If the IOTA Model were not implemented, then IOTA participants would not have the performance-based upside and downside risk payments to increase their organ offer acceptance rate. Therefore, pre-pandemic growth rates for deceased donor kidney transplants would be expected to continue during the projection period. The living donor kidney transplant growth rate is also expected to continue close to pre-pandemic rates in the absence of the model.

One initiative and one recent reform have the potential to impact the IOTA study population, even in the absence of the proposed model. First, the OPTN Modernization Initiative that HRSA announced in March 2023 includes several actions to strengthen accountability, transparency, equity, and performance in the OPTN.[344] Some of the proposed OPTN Modernization Initiative actions that are relevant to the IOTA Model's target population include data dashboards detailing individual transplant center and organ procurement organization data on organ retrieval, waitlist outcomes, and transplants, and demographic data on organ donation and transplant will be made available to patients. In the absence of the IOTA Model, the OPTN Modernization Initiative has the potential to incentivize IOTA participants to improve upon some of the IOTA model's incentive domains, such as improving the organ offer acceptance rate, post-transplant outcomes, and patient equity.

Second, the Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act (H.R. 5534; also known as the Immuno Bill) passed in November 2020, which stipulates lifelong coverage for immunosuppressive drugs for kidney transplant recipients, has the potential to improve patient survival.[345]

[342] King, K.L., Husain, S.A., Schold, J.D., Patzer, R.E., Reese, P.P., Jin, Z., Ratner, L.E., Cohen, D.J., Pastan, S.O., & Mohan, S. (2020). Major Variation across Local Transplant Centers in Probability of Kidney Transplant for Wait-Listed Patients. Journal of the American Society of Nephrology, 31(12), 2900–2911. *https://doi.org/10.1681/ASN.2020030335*.

[343] Organ Procurement and Transplant Network/Scientific Registry of Transplant (OPTN/SRTR). ''OPTN/SRTR YYYY Annual Data Report: Kidney. Supplemental Data Tables.'' Where YYYY is for report years 2015, 2018, 2019, 2020, and 2021. *https://www.srtr.org/reports/optnsrtr-annual-data-report/*.

[344] HHS. 2023. ''HRSA Announces Organ Procurement and Transplantation Network Modernization Initiative.'' *https://www.hhs.gov/about/news/2023/03/22/hrsa-announces-organ-procurement-transplantation-network-modernization-initiative.html*.

[345] CMS. 2022. ''Medicare Program; Implementing Certain Provisions of the Consolidated

Continued

Beginning January 1, 2023, the Medicare Part B Immunosuppressive Drug benefit covers immunosuppressive drugs beyond 36 months for eligible kidney transplant recipients that do not have other health coverage for immunosuppressive drugs. The most current statistics of post-transplant patient survival are reported by Hariharan et al.[346] The authors used data from the OPTN/SRTR and found that post-deceased donor kidney transplant patient survival rates at years 1 and 3 are 97.1 percent and 93.3 percent, respectively, for transplantation taking place during 2016–2019. Post-living donor kidney transplant patient survival rates are 99.1 percent and 96.5 percent during the same period. These rates decrease over the longer term. For kidney transplantation during 2008–2011, patient survival rates at 10 years are 66.9 percent for deceased donor kidney transplants and 81.3 percent for living donor kidney transplants. The authors project that survival rates will continue to improve, explaining that the decline in survival starting 3 years after transplantation has been attributed to, and coincides with, the discontinuation of insurance coverage for long-term immunosuppressive medications.

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), Executive Order 14094 entitled ''Modernizing Regulatory Review'' (April 6, 2023), 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).

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). The Executive Order 14094 entitled ''Modernizing Regulatory Review'' (hereinafter, the Modernizing E.O.) amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended 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 $200 million or more in any 1 year (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (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) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) ($200 million or more in any 1 year). Based on our estimates from the CMS Office of the Actuary, OMB's Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is not significant per section 3(f)(1). Accordingly, we have prepared an RIA that to the best of our ability presents the costs and benefits of the rulemaking. Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act), OIRA has also determined that this rule does not meet the criteria set forth in 5 U.S.C. 804(2). We solicit comment on the RIA.

C. Detailed Economic Analysis

Several important factors have been identified that lead to the discard of donated kidneys, including significant increased cost to hospitals for transplanting organs from older donors and/or donors with comorbidities. Value-based payments that reward hospitals for increasing the number of transplants as well as related quality and process measures may improve the acceptance of offered organs and outcomes for patients.[347] A stochastic model was constructed to estimate the financial impact of the IOTA model. When possible, assumptions were informed by historical data. Transplant hospital adult transplant counts by donor type and recipients' primary source of payment were obtained from the SRTR dashboard.[348] Organ offer acceptance ratios [349] and survival rate data (for both years 1 and 3) [350] were analyzed from SRTR's program-specific statistics and transplant hospital-level data on kidney transplants. The SRTR data source includes data on all transplant donors, candidates, and recipients in the U.S.

IOTA participants would receive upside or downside risk payments based on their performance across three domains: achievement, efficiency, and quality. The three domains would measure certain metrics and award points as shown in the following Table 12:

Appropriations Act, 2021 and Other Revisions to Medicare Enrollment and Eligibility Rules. Final Rule.'' **Federal Register** 87 FR 66454: 66454–66511.

[346] Hariharan S, Irani AK, Danovitch G (2023). ''Long-Term Survival after Kidney Transplantation.'' *New England Journal of Medicine.* 385:729–43. *https://www.nejm.org/doi/full/10.1056/NEJMra2014530.*

[347] Cooper, M. et. al. (2018). Report of the National Kidney Foundation Consensus Conference to Decrease Kidney Discards. *Journal of Clinical Transplantation and Translational Research, https://doi.org/10.1111/ctr.13419.*

[348] Scientific Registry of Transplant Recipients. Adult Recipient Transplants By Donor Type, Center: U.S. Transplants Performed: January 1, 1988–July 31, 2023; For Organ = Kidney; Include: Transplant Year & Recipient Primary Source of Payment. *https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/.* Accessed October 17, 2022.

[349] Scientific Registry of Transplant Recipients. National Center Level Data by Organ: Kidney CSRS Final Tables, Table B11 & Figures B10–B14. *https://www.srtr.org/reports/program-specific-reports/.* Accessed May 25, 2023.

[350] Scientific Registry of Transplant Recipients. National Center Level Data by Organ: Kidney CSRS Final Tables, Tables C5–C12 Figures C1–C20. *https://www.srtr.org/reports/program-specific-reports/.* Accessed May 25, 2023.

TABLE 12: IOTA PERFORMANCE DOMAINS

Domain	Metrics Description	Points
Achievement	The number of transplants performed relative to a target, adjusted for health equity population. Rolling baseline.	60
Efficiency	**20 pts:** Organ offer acceptance rate**,** which is a ratio of observed versus expected organ offer acceptances.	20
Quality	**10 pts**: Composite Post-transplant outcome measure	20
	10 pts: Quality measure set: **4 pts**: CollaboRATE Shared Decision-Making Score (CBE ID:3327). **2 pts**: Colorectal Cancer Screening (COL) (CBE ID: 0034). **4 pts**: The 3-Item Care Transition Measure (CTM-3) (CBE ID: 0228).	
Total Possible		100

The upside risk payment would be a lump sum payment paid by CMS to the IOTA participants that achieve high final performance scores. Conversely, the downside risk payment would be a lump sum payment paid to CMS by the IOTA participants with low final performance scores. The performance-based payments would be based on the following thresholds. Total scores of 60 and above would result in a maximum upside risk payment of $8,000, as shown in equation 4. Scores below 60 would fall into the neutral zone with no upside or downside risk payment in PY 1. After the first PY, scores from 41 to 59 would fall in the neutral zone, and scores of 40 and below would receive a downside risk payment. The maximum downside risk payment in the model would be $2,000, as shown in equation 5. This performance-based payment would then be multiplied by the total number of kidney transplants furnished by the IOTA participant to attributed patients for which model payments apply during the PY.

Equation 4: IOTA Upside Risk Payment for Scores of 60 and Above

$$\textit{IOTA Lump Sum Payment} = \$8{,}000 * ((\textit{Final Performance Score} - 60)/40) * \textit{Medicare Kidney Transplants}$$

Equation 5: IOTA Downside Risk Payment for Scores of 40 and Below

$$\textit{IOTA Performance Payment} = \$2{,}000 * ((40 - \textit{Final Performance Score})/40) * \textit{Medicare Kidney Transplants}$$

CMS randomly selected half of all DSAs in the country and all eligible IOTA participants within those DSAs and applied assumptions for transplant growth and performance on other domains affecting the incentive formula for purposes of estimating impacts in this portion of the rule. Random variables accounted for variation in transplant growth and transplant hospital-level performance on other measures. A pivotal uncertainty relates to the potential growth in transplants as a result of upside and downside risk payments presented by the model. The current share of deceased donated kidneys that are discarded is roughly 20 percent.[351] [352] Such growth was assumed to phase in over a 2- to 5-year period using a skewed distribution, with a gradual phase-in of 5 years being the most likely outcome.

For IOTA participants randomized into the model, assumptions were also made for gradual improvement over baseline kidney acceptance rates, with individual IOTA participants assumed to have, in year 1, up to a 10-percent chance (up to a 20-percent chance by year 2, etc.) of increasing their acceptance ratio by between 20 to 80 percentage points and maintaining such simulated improvement in ensuing model years. The share of IOTA participants receiving passing confidence intervals for the 1-year and 3-year failure ratios was assumed to be roughly 95 percent in year 1, gradually improving by about half of a percentage point per year. Please see section III.C.5.e.(1). of this rule for the discussion on post-transplant outcomes.

CMS assumed that all quality measures would be successfully reported by all IOTA participants in model PYs 1 and 2 (resulting in uniformly maximum scores in that domain). Table II illustrates below that on average, 60 percent of IOTA participants were assumed to achieve maximum quality scores throughout the remaining 4 years of the model; 30 percent were assumed to gradually improve from scores of 5 to 8 in year 3 to scores of 5 to 9 by year 6; and 10 percent were assumed to improve from scores of 2 to 7 in year 3 to scores of 3 to 8 by year 6. We assumed that most IOTA participants would be able to maximize scores early in the testing period and a minority would require more time to reach a higher scoring level. Actual scoring distributions will depend on how CMS ultimately sets targets and how IOTA participants respond.

[351] Li MT, King KL, Husain SA, et al. 2021. ''Deceased Donor Kidneys Utilization and Discard Rates During COVID–19 Pandemic in the United States.'' *Kidney Int Rep;* 6(9): 2463–2467. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8419126/.*

[352] Robinson A, Booker S, Gauntt K, UNOS Research Department. 2022. ''Eliminate Use of DSA and Region from Kidney Allocation One Year Post-Implementation Monitoring Report.'' *OPTN Kidney Transplantation Descriptive Data Report. https://optn.transplant.hrsa.gov/media/p2oc3ada/data_report_kidney_full_20220624_1.pdf.*

TABLE II: QUALITY SCORE POINTS BY SHARE OF IOTA PARTICIPANTS AND MODEL YEAR

Share of IOTA Participants	Quality Points by Measurement Year			
	MY1	MY2	MY3	MY4 - MY6
10%	10	10	2-7	3-8
30%	10	10	5-8	5-9
60%	10	10	10	10

Table III later in this section shows the projected impacts for upside and downside risk payments, transplants, and Federal spending. Although transplant recipients with any type of insurance may benefit from a transplant hospital's participation in the model, model payments will be based on the number of transplant recipients who are beneficiaries with Medicare fee-for-service (FFS) coverage and beneficiaries enrolled in Medicare as a secondary payer. In any given year, about 30 percent of IOTA participants are projected to receive upside risk payments (ranging from 20 to 40 percent), with only about half of that number of IOTA participants projected to have a downside risk payment in any of years 2 through 6 (ranging from 10 to 23 percent). However, the magnitude of the average downside risk payment is relatively small, and the cumulative projected upside risk payments to IOTA participants, amounting to $36 million, are over 30 times the magnitude of a cumulative $1 million in projected receipts from downside risk payments from IOTA participants to CMS. The amount of projected savings from new transplants was greater than the net cost of payments in 85 percent of simulation trials. Mean net savings totaled $65 million over 6 years, ranging from a savings of $151 million to a cost of $11 million at the 10th and 90th percentiles.

TABLE III: PROJECTED IMPACT OF UPSIDE/DOWNSIDE RISK PAYMENTS, KIDNEY TRANSPLANTS, AND NET FEDERAL SPENDING

(Projected savings allocated to year of transplant; dollars in millions)

							6-Year Totals		
	2025	2026	2027	2028	2029	2030	Mean	10th Percentile	90th Percentile
Upside Risk Payments	$5	$6	$6	$6	$7	$7	$36	$27	$45
Downside Risk Payments	$0	$0	$0	$0	$0	$0	−$1	−$2	−$1
Total Net Payments	**$5**	**$6**	**$5**	**$6**	**$6**	**$7**	**$35**	$26	$44
Added Transplants	114	244	388	542	652	685	2,625	896	4,669
Impact on FFS Spending	**−$4**	**−$8**	**−$14**	**−$20**	**−$26**	**−$28**	**−$100**	**−$151**	**−$23**
Mean Net Savings	**$1**	**−$2**	**−$8**	**−$14**	**−$19**	**−$21**	**−$65**	−$151	$11

In Table III, negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase in Medicare spending. The mean net savings results were generated from the average of 400 individual simulation trials and the results for the percentiles are from the top 10th and 90th percentiles of the 400 individual simulations. The outcomes in each row do not necessarily flow from the same trial in the model at the 10th and 90th percentiles. For example, the 90th percentile for added transplants more likely corresponds to the trial that produced the 10th percentile in impact on FFS spending from those transplants (because spending is reduced when transplants grow).

There is a wide range of potential changes in Federal spending for each new transplant. Savings on avoided dialysis may in many cases be exceeded when transplants are especially complex and post-transplant complications are more likely, for example when deceased organs have a high kidney donor profile index and/or recipients are of advanced age.[353] But even in such cases Federal savings can be substantial if Medicare is not primary payer at time of transplant or the beneficiary eventually returns to private insurance post-transplant. We relied on the savings per transplant estimate published in the ESRD Treatment Choices (ETC) model final rule [354] to account for different primary payer scenarios at the time of transplant, as well as the likelihood that the beneficiary would have remained on Medicare after transplantation. For the ETC model, OACT produced a 10-year savings to Medicare of approximately $32,000 per beneficiary for a deceased donor kidney transplant with a high-kidney donor profile index. For the proposed IOTA model, we assumed the average Federal spending impact could range from a cautious $20,000 increase to optimistically at most a $100,000 savings per additional transplant (mean assumption being a $40,000 savings).

The mean assumption of $40,000 in savings is marginally higher than the ETC model's 10-year estimated savings to Medicare of approximately $32,000 per beneficiary for a deceased donor kidney transplant with a high-kidney donor profile index because it includes at least some potential for an increase in other types of transplants. The 10-year estimated savings to Medicare of approximately $32,000 per beneficiary used in the ETC model based on deceased donor, high-kidney donor profile transplants was assumed because of the relatively limited focus that model appeared to have on improving the number of transplants and outcomes

[353] Axelrod DA, Schnitzler MA, Xiao H, et al. 2018. ''An Economic Assessment of Contemporary Kidney Transplant Practice.'' *American Journal of Transplantation* 18: 1168–1176. *https://pubmed.ncbi.nlm.nih.gov/29451350/.*

[354] Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures, 85 FR 61335 (September 29, 2020) (codified at 45 CFR part 512, subpart A).

for transplants. By comparison, the estimate for the IOTA Model still focused on deceased donor kidneys, but this model warranted a marginally higher savings per transplant estimate, allowing for the mean assumption of $40,000 in savings. To determine the outer bounds of the assumption, we identified individual points in our organ-type/payer matrix that ranged from a $100,000 increase in costs to $200,000 (or wider) in savings, so the bounds we chose for the estimate were based on realizing new transplants were going to be mixed across the matrix and not all congregated at an extreme end on one side or the other (keeping in mind that they will likely come mostly from decedent donor kidneys). We assumed that kidney transplant savings would accumulate in the year of the transplant even though the cost of the transplant would, in practice, lead to higher spending in the first year (unless Medicare was not the primary payer). It would likely take longer than the 6 model years for the cumulative net savings projected in Table III to ultimately materialize. The timing of when savings would accumulate could not be estimated with more precision for the following reasons. Savings could range from being virtually immediate if new transplants occur when a beneficiary is not Medicare primary payer status, to being backloaded if the beneficiary receives the transplant when Medicare is primary payer, to being a net cost if the beneficiary transplant fails within a short period after transplant. Given those uncertainties, and the underlying uncertainties about where the new transplants will materialize from (by donor and recipient), we were not able to imply more precision than we were able to model from the evidence.

While the proposed model is focused on transplant outcome measures that would be calculated by CMS, there would likely be some additional burden for compliance for the IOTA participants (that is, transplant hospitals). To estimate the compliance cost we focused on the proposed patient-reported survey measure. We estimate that the average IOTA participant would perform 50 surveys per year and that it would take a clinician 20 minutes to complete the survey. Using base wage information from BLS for a nurse practitioner, we estimate the cost of completing these surveys to be $59.94 per hour. The base wage is then doubled [$59.94 × 2] to account for fringe benefits and overhead to equal an estimated cost of $119.88 per hour.[355] The cost of completing these surveys would then be $1,998 per hospital per year [50 surveys × (⅓) hour per survey × $119.88 hourly wage]. Therefore, the total cost would come out to $179,820 to complete the surveys based on the assumption that 90 active transplant hospitals will be selected as IOTA participants [$1,998 × 90 hospitals = $179,820]. Average total revenue for the transplant hospitals that may be selected to be an IOTA participant using inpatient hospital codes DRG–008 simultaneous pancreas-kidney transplant and DRG–652 kidney transplant generated from adult Medicare FFS beneficiaries with Medicare as their primary payer was $1.2 million in calendar year 2022. Therefore, the $1,998 cost per IOTA participant to complete the patient-reported survey measure would represent 0.2 percent of the estimated total annual revenue per IOTA participant from DRGs 653 and 008 when Medicare is the primary payer.

1. Regulatory Review Cost Estimation

We estimate the time it will take for a medical and health services manager to review the rule to be 5.33 hours [80,000 words/250 words per minute/60 minutes = 5.33 hours]. Using the wage information from the Bureau Labor of Statistics (BLS) for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $123.06 per hour, including overhead and fringe benefits.[356] The cost of reviewing the rule would therefore be a $655.91 per hospital [5.33 hours × $123.06 per hour = $655.91] or a total cost of $59,031.90 [$655.91 × 90 hospitals = $59,031.90]. Using information from the OPTN, we estimate 230 active kidney transplant hospitals that are the potential IOTA participants would review this rule for a total cost of $150,859.30 [$655.91 per hospital × 230 hospitals = $150,859.30].[357] In addition, the $655.91 cost per IOTA participant to complete the regulatory review would represent 0.1 percent of the estimated total annual revenue from DRGs 653 and 008 when Medicare is the primary payer.

D. Alternatives Considered

Two alternative model specifications were tested for comparison to the results in Table III. The first alternative model specification estimated the impact of including MA beneficiaries as eligible transplant recipients for purposes of upside and downside risk payments to IOTA participants. Currently, MA beneficiaries represent approximately 50 percent of Medicare ESRD beneficiaries receiving transplants, and this share is expected to grow. Over the 6-year period, the projected costs from total net payments increased slightly from $35 million in the primary model specification to $47 million in this first alternative. As expected, most of the impact of the inclusion of MA beneficiaries was observed in added transplants, which increased from 2,625 to 3,428 and from $100 million to $133 million in savings. When MA beneficiaries were included, the mean net savings increased marginally from the primary model specification to $86 million over 6 years, ranging from a savings of $201 million to a cost of $10 million at the 10th and 90th percentiles.

The second alternative model specification excluded MA beneficiaries (that is, returned to the population of the primary model specification) and tested the use of a continuous grading scale instead of bands in the achievement domain for transplants for which the upside risk payments become much more generous (particularly for IOTA participants that would otherwise have resulted in a neutral outcome). The continuous grading scale works by taking the first year equity-adjusted-transplants-to-target ratio for each IOTA participant and divides that by 2.5 times 100 and has a ceiling of 60 points. The reason why the continuous grading scale is costly is because it provides upside risk payments to a much larger group of IOTA participants because it gives sliding scale partial credit for IOTA participants that get above 1.00 in their ratio whereas the proposed method makes them go all the way to a ratio of 1.25 before they get more than 30 points (for example, they jump up to 45 points). Using the continuous grading scale approach, the cumulative projected upside risk payments grew from $36 million in the primary model specification to $118 million in this second alternative. The projected receipts from downside risk payments levied and the projected savings from new transplants were similar to the estimated impacts under the primary model specification. Overall, the mean

[355] Guidelines for the adjustment in base wages is based on the following report: Office of the Assistant Secretary for Planning and Evaluation (ASPE). 2017. ''Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices.'' *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.*

[356] Bureau of Labor Statistics (BLS). 2022. ''Occupational Employment and Wage Statistics.'' *https://www.bls.gov/oes/current/oes_nat.htm.*

[357] *https://optn.transplant.hrsa.gov.*

net savings for the second alternative significantly changed in sign and magnitude from the primary specification to $15 million in increased costs over 6 years, ranging from a savings of $77 million to a cost of $90 million at the 10th and 90th percentiles. This alternative model specification was not selected because we chose to create bands of performance rather than a continuous scale to provide participants with clear end points to incentivize performance to hit specific thresholds.

E. Impact on Beneficiaries

The upside and downside risk payments in this model are expected to at least marginally increase the number of kidney transplants provided to beneficiaries with ESRD. This proposed model is projected to result in over 2,600 new transplants over the 6-year model performance period. Evidence shows that kidney transplants extend patients' lives and that such benefits have been increasing despite unfavorable trends in terms of donor and recipient risk factors.[358] Even if added transplants most often were to involve high Kidney Donor Profile Index (KDPI) organs (that are most often discarded historically), the average recipient would still be expected to benefit from increased quality of life and longevity.[359] In addition—though we did not explicitly assume specific benefits to beneficiaries—the model would include quality measures aimed at improving outcomes even for transplants that would have otherwise occurred absent the model. IOTA participants would be incentivized to improve graft survival outcomes (measured at 1 year post-transplant). The model could also improve the efficiency with which hospitals interact with organ procurement organizations and reduce the time from deceased organ donation to transplant surgery. These and other elements of the model have the potential to improve outcomes for the wider group of transplant patients beyond the fraction assumed to receive transplants under the proposed model.

F. Accounting Statement and Table

The annualized monetized benefits and transfers in Table IV were calculated based on constant payments and constant interest rates. Using the row labeled Total as an example for how the results were calculated, the primary estimate of $10 million in total savings was based on a 7 percent discount rate, with a 6-year study period, and a 7 percent net present value of $45.6 million in savings. Net present value for the primary estimate was based on the IOTA Model's mean net savings estimate for years 2025–2030 reported in the bottom row of Table III. The minimum and maximum annualized monetized total benefits and transfers reported in Table IV use the same calculation as the primary estimate, with the exception of the annual mean net savings replaced with the IOTA model's annual mean net savings for the 10th and 90th percentiles.

TABLE IV: ACCOUNTING STATEMENT

Annualized monetized benefits and transfers (negative indicates savings). Dollars in millions.

	Primary Estimate	Minimum Estimate	Maximum Estimate	Source Citation
Costs to Medicare for Upside Risk Payments to IOTA Participants	$6	$4	$8	RIA Table III
Costs to IOTA Participants for Downside Risk Payments	$0	$0	$0	RIA Table III
Benefits via Savings from Increased Transplants	-$16	-$29	-$4	RIA Table III
Total	**-$10**	**-$23**	**$2**	**RIA Table III**

Notes: The total may not equal the sum of the preceding rows due to rounding. The costs to IOTA participants for negative payments are less than a million dollars for the primary, minimum, and maximum estimates.

TABLE V: ADDITIONAL ESTIMATED COSTS FOR 2025-2030

Category	Costs	Source Citation
Burden to IOTA participants	$90,000	section IV.C. Detailed Economic Analysis
Regulatory review	$151,000	section IV.C. Detailed Economic Analysis

G. Regulatory Flexibility Act (RFA)

Effects on IOTA participants in the proposed model include the potential for additional upside risk payments from CMS to the IOTA participant of up to $8,000 per eligible kidney transplant or downside risk payments from the IOTA participant to CMS of up to $2,000 per eligible kidney transplant (refer to section IV.C. of this proposed rule (Detailed Economic Analysis) for a description of how upside and downside risk payments are calculated in the model). We project that payouts will far exceed the relatively small sum of downside risk payments expected over the 6-year model performance period. Only about $1 million in total downside risk payments are expected over 6 years from approximately 10 to 23 percent of IOTA participants expected to be charged downside risk payments from year to year. By contrast, we project over 6 years that $36 million in total upside risk payments would be made to between 20 to 40 percent of IOTA participants expected to earn payments in the model from year to year.

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. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year). Although many IOTA participants

[358] Hariharan S., Irani A.K., Danovitch G., (2023). ''Long-Term Survival after Kidney Transplantation.'' *New England Journal of Medicine.* 385:729–43. *https://www.nejm.org/doi/full/10.1056/NEJMra2014530.*

[359] Axelrod D.A., Schnitzler M.A., Xiao H., et al. 2018. ''An Economic Assessment of Contemporary Kidney Transplant Practice.'' *American Journal of Transplantation* 18: 1168–1176. *https://pubmed.ncbi.nlm.nih.gov/29451350/.*

may be small entities as that term is used in the RFA, kidney transplants only represent a small fraction of the revenue such hospitals generate, and even the largest per-transplant downside risk payment of $2,000 (which notably is expected to be a very rare outcome in general) would not represent a significant economic impact. Additional sources of financial burden on IOTA participants to consider include the estimated cost of $1,998 per IOTA participant per year to complete the patient-reported survey that is included in the quality measure set and the one time cost of $655.91 per IOTA participant to have their medical and health services manager review this rule.

As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this proposed rule. Therefore, the Secretary has certified that this proposed rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 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 believe this proposed rule will not have a significant impact on small rural hospitals since small rural hospitals do not have the resources to perform kidney transplants. 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.

H. Unfunded Mandates Reform Act (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 2024, that threshold is approximately $183 million. This proposed does not mandate any requirements for State, local, or tribal governments, or for the private sector.

I. 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. This proposed rule would not have a substantial direct effect on State or local governments, preempt States, or otherwise have a Federalism implication.

VI. 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.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on April 30, 2024.

List of Subjects in 42 CFR Part 512

Administrative practice and procedure, Health facilities, Medicare, Recordkeeping requirements.

For the reasons set forth in the preamble the Centers for Medicare & Medicaid Services proposes to amend 42 CFR part 512 as follows:

■ 1. The part heading for part 512 is revised to read as follows:

PART 512—STANDARD PROVISIONS FOR INNOVATION CENTER MODELS AND SPECIFIC PROVISIONS FOR THE RADIATION ONCOLOGY MODEL AND THE END STAGE RENAL DISEASE TREATMENT CHOICES MODEL

■ 2. The authority for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

■ 3. The heading of subpart A is revised to read as follows:

Subpart A—Standard Provisions for Innovation Center Models

■ 4. Revise § 512.100 to read as follows.

§ 512.100 Basis and scope.

(a) *Basis.* This subpart implements certain standard provisions for Innovation Center models, as that term is defined in this subpart.

(b) *Scope.* (1) The regulations in this subpart apply to each Innovation Center model that—

(i) Began its first performance period before January 1, 2025, if incorporated by reference, in whole or in part, into the Innovation Center model's governing documentation; or

(ii) Begins its first performance period on or after January 1, 2025, unless otherwise specified in the Innovation Center model's governing documentation.

(2) This subpart sets forth the following:

(i) Basis and scope.

(ii) Definitions.

(iii) Beneficiary protections.

(iv) Cooperation in model evaluation and monitoring.

(v) Audits and record retention.

(vi) Rights in data and intellectual property.

(vii) Monitoring and compliance.

(viii) Remedial action.

(ix) Innovation Center model termination by CMS.

(x) Limitations on review.

(xi) Miscellaneous provisions on bankruptcy and other notifications.

(xii) Reconsideration review processes.

(3) Except as specifically noted in this subpart, these regulations do not affect the applicability of other provisions affecting providers and suppliers under Medicare FFS, including provisions regarding payment, coverage, or program integrity.

■ 5. Section 512.110 is amended by—

■ a. Adding the definition of ''Governing documentation'' in alphabetical order;

■ b. Revising the definitions of ''Innovation Center model'', ''Innovation Center model activities'', ''Model beneficiary'', and ''Model participant''; and

■ c. Adding the definitions of ''Performance period'' and ''Standard provisions for Innovation Center models'' in alphabetical order.

The additions and revisions read as follows:

§ 512.110 Definitions.

* * * * *

Governing documentation means the applicable Federal regulations, and the model-specific participation agreement, cooperative agreement, and any addendum to an existing contract with CMS, that collectively specify the terms of the Innovation Center model.

* * * * *

Innovation Center model means an innovative payment and service delivery model tested under the authority of section 1115A(b) of the Act,

including a model expansion under section 1115A(c) of the Act.

Innovation Center model activities means any activities affecting the care of model beneficiaries related to the test of the Innovation Center model.

* * * * *

Model beneficiary means a beneficiary attributed to a model participant or otherwise included in an Innovation Center model.

Model participant means an individual or entity that is identified as a participant in the Innovation Center model.

* * * * *

Performance period means the period of time during which an Innovation Center model is tested and model participants are held accountable for cost and quality of care; the performance period for each Innovation Center model is specified in the governing documentation.

* * * * *

Standard provisions for Innovation Center models means the provisions codified in subpart A of this part.

* * * * *

■ 6. Section 512.190 is added to read as follows:

§ 512.190 Reconsideration review process.

(a) *Applicability of this section.* This section is only applicable to the following:

(1) Innovation Center models that have waived section 1869 of the Act, or where section 1869 of the Act is not applicable for model participants.

(2) Model participants, unless the governing documentation for the Innovation Center model States otherwise.

(b) *Right to reconsideration.* The model participant may request reconsideration of a determination made by CMS in accordance with an Innovation Center model's governing documentation only if such reconsideration is not precluded by section 1115A(d)(2) of the Act, this subpart, or the governing documentation for the Innovation Center model for which CMS made the initial determination.

(1) A request for reconsideration by the model participant must satisfy all of the following criteria:

(i) Must be submitted to a designee of CMS (reconsideration official) who—

(A) Is authorized to receive such requests; and

(B) Did not participate in the determination that is the subject of the reconsideration request, or, if applicable, the timely error notice review process.

(ii)(A) Must include a copy of the initial determination issued by CMS; and

(B) Must contain a detailed, written explanation of the basis for the dispute, including supporting documentation.

(iii) Must be made within 30 days of the date of the initial determination for which reconsideration is being requested via email to an address as specified by CMS in the governing documentation for the Innovation Center model for which CMS made the initial determination.

(2) Requests that do not meet the requirements of paragraph (b)(1) of this section are denied.

(3) Within 10 business days of receiving a request for reconsideration, the reconsideration official sends CMS and the model participant a written acknowledgement of receipt of the reconsideration request. This acknowledgement sets forth all of the following:

(i) The review procedures.

(ii) A schedule that permits each party to submit position papers and documentation in support of the party's position for consideration by the reconsideration official.

(4) If the request is regarding a model-specific payment and the governing documentation specifies an initial timely error notice process, the model participant must satisfy the timely error notice requirements specified in the governing documentation before submitting a reconsideration request under paragraph (b) of this section. In the event that the model participant fails to timely submit an error notice with respect to a particular model-specific payment, the reconsideration review process would not be available to the model participant with regard to that model-specific payment.

(c) *Standards for reconsideration.* (1) The parties must continue to fulfill all responsibilities and obligations under the governing documentation during the course of any dispute arising under the governing documentation.

(2) The reconsideration consists of a review of documentation that is submitted timely and in accordance with the standards specified by the reconsideration official and are enumerated in paragraph (b)(3) of this section.

(3) The burden of proof is on the model participant to demonstrate to the reconsideration official with clear and convincing evidence that the determination is inconsistent with the terms of the governing documentation.

(d) *Reconsideration determination.* (1) The reconsideration determination is based solely upon both of the following:

(i) Position papers and supporting documentation that meet both of the following:

(A) Submitted timely to the reconsideration official in accordance with the schedule specified in paragraph (b)(3)(ii) of this section.

(B) The standards for submission under paragraph (b)(1) of this section.

(ii) Documents and data that were timely submitted to CMS in the required format before CMS made the determination that is the subject of the reconsideration request.

(2)(i) The reconsideration official issues the reconsideration determination to CMS and to the model participant in writing.

(ii) Absent unusual circumstances, in which case the reconsideration official reserves the right to an extension upon written notice to the model participant, the reconsideration determination is issued within 60 days of receipt of timely filed position papers and supporting documentation in accordance with the schedule specified in paragraph (b)(3)(ii) of this section.

(3) The reconsideration determination is final and binding 30 days after its issuance, unless the model participant or CMS timely requests review of the reconsideration determination in accordance with paragraphs (e)(1) and (2) of this section.

(e) *CMS Administrator review.* The model participant or CMS may request that the CMS Administrator review the reconsideration determination. The request must meet both of the following:

(1) Be made via email within 30 days of the date of the reconsideration determination to the address specified by CMS.

(2) Include a copy of the reconsideration determination and a detailed written explanation of why the model participant or CMS disagrees with the reconsideration determination.

(3) The CMS Administrator promptly sends the parties a written acknowledgement of receipt of the request for review.

(4) The CMS Administrator sends the parties notice of the following:

(i) Whether the request for review is granted or denied.

(ii) If the request for review is granted, the review procedures and a schedule that permits each party to submit a brief in support of the party's position for consideration by the CMS Administrator.

(4) If the request for review is denied, the reconsideration determination is final and binding as of the date the request for review is denied.

(5) If the request for review is granted all of the following occur:

(i) The record for review consists solely of—

(A) Timely submitted briefs and the evidence contained in the record of the proceedings before the reconsideration official; and

(B) Evidence as set forth in the documents and data described in paragraph (d)(1)(ii) of this section.

(ii) The CMS Administrator reviews the record and issues to CMS and to the model participant a written determination.

(iii) The written determination of the CMS Administrator is final and binding as of the date the written determination is sent.

■ 7. Add subpart D to read as follows:

Subpart D—Increasing Organ Transplant Access (IOTA) Model

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Subpart D—Increasing Organ Transplant Access (IOTA) Model

§ 512.400 Basis and scope.

(a) *Basis.* This subpart implements the test of the Increasing Organ Transplant Access (IOTA) Model under section 1115A(b) of the Act.

(b) *Scope.* This subpart sets forth the following:

(1) The method for selecting IOTA participants.

(2) The patient population.

(3) The methodology for IOTA participant performance assessment and scoring for purposes of the achievement domain, efficiency domain, and quality domain, including beneficiary attribution and transplant target calculation.

(4) The schedule and methodologies for the upside risk payment and downside risk payment.

(5) Data sharing.

(6) Other IOTA Model requirements.

(7) Beneficiary protections.

(8) Financial arrangements.

(9) Monitoring.

(10) Evaluation.

(11) Termination.

(12) Except as specifically noted in this subpart, the regulations under this subpart do not affect the applicability of other provisions affecting providers and suppliers under Medicare fee for service, including the applicability of provisions regarding payment, coverage, or program integrity.

(c) *Applicability.* IOTA participants are subject to the standard provisions for Innovation Center models specified in subpart A of this part and in subpart K of part 403 of this chapter.

§ 512.402 Definitions.

For purposes of this subpart, the following definitions apply.

Achievement domain means the performance assessment category in which CMS assesses the IOTA participant's performance based on the number of transplants performed relative to the transplant target, subject to the health equity performance adjustment, as described in § 512.424.

Alignment payment means a payment from an IOTA collaborator to an IOTA participant that is made in accordance with a sharing arrangement.

Annual attribution reconciliation means the yearly process in which CMS—

(1) Creates the final list of each IOTA participant's attributed patients for the prior performance year by retrospectively de-attributing from each IOTA participant any attributed patients that satisfy a criterion for de-attribution under § 512.414(c).

(2) Creates a final list of each IOTA participant's attributed patients who remain attributed for the performance year being reconciled, subject to the attribution criteria under §§ 512.414(b)(1) and (2).

Annual attribution reconciliation list means the final cumulative record of attributed patients that CMS generates annually for whom each IOTA participant is accountable for during the applicable PY as described at § 512.414(c)(2).

Attributed patient means an IOTA waitlist patient or an IOTA transplant patient.

Attribution means the process by which CMS identifies the patients for whom each IOTA participant is accountable during the model performance period, as described in § 512.414.

Baseline year means a 12-month period within a 3-year historical baseline period, that begins 48 months (or 4 years) before the start of each model PY and ends 12 months (or 1 year) before the start of each model PY, as described in § 512.424.

Bypassed response means an organ offer not received due to expedited placement or a decision by a kidney transplant hospital to have all of its kidney transplant waitlist patients skipped during the organ allocation process based on a set of pre-defined filters selected by the kidney transplant hospital matching the characteristics of the potential organ to be transplanted.

Critical access hospital (CAH) means a hospital as defined in section 1861(mm)(1) of the Act.

Change in Control means at least one of the following:

(1) The acquisition by any ''person'' (as this term is used in sections 13(d) and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d–3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of the IOTA participant representing more than 50 percent of the IOTA participant's outstanding voting securities or rights to acquire such securities.

(2) The acquisition of the IOTA participant by any other individual or entity.

(3) Any merger, division, dissolution, or expansion of the IOTA participant.

(4) The sale, lease, exchange, or other transfer (in one transaction or a series of transactions) of all or substantially all the assets of the IOTA participant.

(5)(i) The approval and completion of a plan of liquidation of the IOTA participant; or

(ii) An agreement for the sale or liquidation of the IOTA participant.

Collaboration agent means an individual or entity that is not an IOTA collaborator and that is a member of a PGP, NPPGP, or TGP that has entered into a distribution arrangement with the same PGP, NPPGP, or TGP in which he or she is an owner or employee, and where the PGP, NPPGP, or TGP is an IOTA collaborator.

Composite graft survival rate means the rolling unadjusted total number of functioning grafts relative to the total number of adult kidney transplants performed, as described in § 512.428.

CORF stands for comprehensive outpatient rehabilitation facility.

Days means calendar days unless otherwise specified by CMS.

Distribution arrangement means a financial arrangement between an IOTA collaborator that is an PGP, NPPGP, or TGP and a collaboration agent for the sole purpose of distributing some or all of a gainsharing payment received by the PGP, NPPGP, or TGP.

Distribution payment means a payment from an IOTA collaborator that is ana PGP, NPPGP, or TGP to a collaboration agent, under a distribution arrangement, composed only of gainsharing payments.

Donation service area (DSA) means a geographical area of sufficient size to ensure maximum effectiveness in the procurement and equitable distribution of organs and that either includes an entire metropolitan statistical area (MSA) or does not include any part of such an area and that meets the standards of subpart G as defined in § 486.302 of this chapter.

Downside risk payment means the lump sum payment the IOTA participant must pay to CMS after the close of a performance year if the IOTA participant's final performance score falls within the ranges specified in § 512.43.

Efficiency domain means the performance assessment category in which CMS assesses the IOTA participant's performance using the organ offer acceptance rate ratio as described in § 512.426.

EFT stands for electronic funds transfer.

Eligible attributed patient means an attributed patient that receives immunosuppressive coverage through Part B or Part D but that does not have secondary insurance that could provide cost sharing support.

Final performance score means the sum total of the scores earned by the IOTA participant across the achievement domain, efficiency domain, and quality domain for a given PY.

Gainsharing payment means a payment that is made from an IOTA participant to an IOTA collaborator, under a sharing arrangement as set forth in § 512.452 and in accordance with § 512.452(c).

Health equity goals means the targeted outcomes relative to the health equity plan performance measures for the first PY and all subsequent PYs.

Health equity performance adjustment means the multiplier applied to each kidney transplant performed for a patient from a low-income population when calculating the transplant target as described under § 512.424(e).

Health equity performance plan measure(s) means one or more quantitative metrics that the IOTA participant uses to measure the reductions in target health disparities arising from the health equity plan interventions.

Health equity plan intervention means the initiative(s) the IOTA participant creates and implements to reduce target health disparities.

Health equity project plan means the timeline for the IOTA participant to implement the IOTA participant's the health equity plan.

HHA means a Medicare-enrolled home health agency.

Hospital means a provider as defined by 1861(u) of the Act.

Improvement benchmark rate means 120 percent of the IOTA participants' performance on organ offer acceptance rate ratio as specified under § 512.426(c)(1)(ii)(A).

Initial attribution means the process by which CMS identifies and prospectively attributes patients who meet the criteria specified under § 512.414(a)(2)(b) to an IOTA participant prior to the model start date.

IOTA activities mean the activities related to promoting accountability for the quality, cost, and overall care for attributed patients and performances across the achievement domain, efficiency domain and quality domain, including any of the following:

(1) Managing and coordinating care.

(2) Encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery.

(3) The provision of items and services pre- or post-transplant in a manner that reduces costs and improves quality.

(4) Carrying out any other obligation or duty under the IOTA Model.

IOTA collaborator means the following Medicare-enrolled providers and suppliers that enter into a sharing arrangement with an IOTA participant:

(1) Nephrologist.

(2) ESRD facility.

(3) Skilled nursing facility (SNF).

(4) Home health agency (HHA).

(5) Long-term care hospital (LTCH).

(6) Inpatient rehabilitation facility (IRF).

(7) Physician.

(8) Nonphysician practitioner.

(9) Therapist in a private practice.

(10) CORF.

(11) Provider or supplier of outpatient therapy services.

(12) Physician group practice (PGP).

(13) Hospital.

(14) CAH.

(15) Non-physician provider group practice (NPPGP).

(16) Therapy group practice (TGP).

IOTA participant means a kidney transplant hospital, as defined at § 512.402, that is required to participate in the IOTA Model under § 512.412.

IOTA transplant patient means a kidney transplant patient who receives a kidney transplant at the age of 18 years of age or older from an IOTA participant at any time during the model performance period and meets the criteria set forth in § 512.412(b)(2).

IOTA waitlist patient means a kidney transplant waitlist ESRD patient, regardless of payer type and waitlist status, who meets all of the following:

(1) Is alive.

(2) 18 years of age or older.

(3) Registered on a waitlist (as defined in § 512.402) to one or more IOTA participants, as identified by the OPTN computer match program.

IRF stands for inpatient rehabilitation facility which must meet all of the following:

(1) The general criteria set forth in § 412.22 0f this chpater.

(2) The criteria to be classified as a rehabilitation hospital or rehabilitation unit set forth in §§ 412.23(b), 412.25, and 412.29 of this chapter for exclusion from the inpatient hospital prospective payment systems specified in § 412.1(a)(1) of this chapter.

Kidney transplant means the procedure in which a kidney is surgically transplanted from a living or deceased donor to a transplant recipient, either alone or in conjunction with any other organ(s).

Kidney transplant hospital means a transplant hospital with a Medicare approved kidney transplant program.

Kidney transplant patient means a patient who is a transplant candidate, as defined in § 121.2, and received a kidney transplant furnished by a kidney transplant hospital, regardless of payer type.

Kidney transplant waitlist patient means a patient who is a transplant candidate, as defined in § 121.2 of this chapter, and who is registered to a waitlist for a kidney at one or more kidney transplant hospitals.

Low-income population means an IOTA transplant patient in one or more of the following groups:

(1) Medicaid beneficiaries.

(2) Medicare-Medicaid dually eligible beneficiaries.

(3) Recipients of the Medicare low-income subsidy.

(4) Recipients of reimbursements from the Living Organ Donation Reimbursement Program administered by the National Living Donor Assistance Center (NLDAC).

(5) The uninsured.

LTCH stands for long-term care hospital that meets the requirements as stated in 42 CFR part 483 subpart B.

Match run means a computerized ranking of transplant candidates based upon donor and candidate medical compatibility and criteria defined in OPTN policies.

Medicare kidney transplant means a kidney transplant furnished to a attributed patient in the IOTA Model whose primary or secondary insurance is Medicare fee for service (FFS), as identified in Medicare FFS claims with MS–DRGs 008, 019, 650, 651, and 652.

Member of the NPPGP or *NPPGP member* means a nonphysician practitioner or therapist who is an owner or employee of an NPPGP and who has reassigned to the NPPGP their right to receive Medicare payment.

Member of the PGP or *PGP member* means a physician, nonphysician practitioner, or therapist who is an owner or employee of the PGP and who has reassigned to the PGP their right to receive Medicare payment.

Member of the TGP or *TGP member* means a therapist who is an owner or employee of a TGP and who has reassigned to the TGP their right to receive Medicare payment.

Missing responses means organ offers that a kidney transplant hospital received from the OPO but did not submit a response (accepting or rejecting) in the allotted 1-hour timeframe from the time the offer was made per OPTN policy 5.6.B.

Model performance period means the 72-month period from the model start date and is comprised of 6 individual performance years.

Model-specific payment means a payment made by CMS only to IOTA participants, or a payment adjustment made only to payments made to IOTA participants, under the terms of the IOTA Model that is not applicable to any other providers or suppliers and includes, unless otherwise specified, both of the following:

(1) The IOTA Model upside risk payment.

(2) The IOTA Model downside risk payment.

Model start date means the date on which the model performance period begins.

National growth rate means the percentage increase or decrease in the number of kidney transplants performed over a 12-month period by all kidney transplant hospitals except for pediatric kidney transplant hospitals, as defined at § 512.402, and kidney transplant hospitals that fall below a low-volume threshold of 11.

National Provider Identifier (NPI) means the standard unique health identifier used by health care providers for billing payors, assigned by the National Plan and Provider Enumeration System (NPPES) in accordance with 45 CFR part 162.

Neutral Zone means the final performance score range in which the IOTA participant neither owes a downside risk payment to CMS or receives an upside-risk payment from CMS, in accordance with § 512.430(b)(2).

Non-pediatric facility means a kidney transplant hospital that furnishes more than 50 percent of their kidney transplants annually to patients 18 years of age or older.

Nonphysician practitioner means (except for purposes of subpart G of this part) one of the following:

(1) A physician assistant who satisfies the qualifications set forth at § 410.74(a)(2)(i) and (ii) of this chapter.

(2) A nurse practitioner who satisfies the qualifications set forth at § 410.75(b) of this chapter.

(3) A clinical nurse specialist who satisfies the qualifications set forth at § 410.76(b) of this chapter.

(4) A certified registered nurse anesthetist (as defined at § 410.69(b) of this chapter).

(5) A clinical social worker (as defined at § 410.73(a) of this chapter).

(6) A registered dietician or nutrition professional (as defined at § 410.134 of this chapter).

NPPGP means an entity that is enrolled in Medicare as a group practice, includes at least one owner or employee who is a nonphysician practitioner, does not include a physician owner or employee, and has a valid and active TIN.

OPTN computer match program means a set of computer-based instructions which compares data on a cadaveric organ donor with data on transplant candidates on the waiting list and ranks the candidates according to OPTN policies to determine the priority for allocating the donor organ(s).

Organ procurement and transplantation network or *OPTN* means the network established under section 372 of the Public Health Service Act.

Organ procurement organization or *OPO* means an entity designated by the Secretary under section 1138(b) of the Act and under 42 CFR 486.304.

Part B and Part D immunosuppressive drug cost sharing support means cost sharing support related to immunosuppressive drugs covered by Medicare Part B, the Medicare Part B Immunosuppressive Drug Benefit (Part B–ID), or Medicare Part D that is provided by an IOTA participant to an eligible attributed patient as codified at § 512.458.

Pediatric kidney transplant hospital means a kidney transplant hospital that performs 50 percent or more of its transplants in a 12-month period on patients under the age of 18.

Performance year (PY) means a 12-month calendar year during the model performance period.

PGP stands for physician group practice.

Physician has the meaning set forth in section 1861(r) of the Act.

Post-transplant period means the 90-day period following an attributed patient's receipt of a kidney transplant.

Preliminary performance assessment and payment calculations means the process by which CMS—

(1) Assesses each IOTA participant's performance in accordance with §§ 512.424, 512.426, 512.428; and

(2) Calculates performance-based payments in accordance with § 512.430.

Provider of outpatient therapy services means an entity that is enrolled in Medicare as a provider of therapy services and furnishes one or more of the following:

(1) Outpatient physical therapy services as defined in § 410.60 of this chapter.

(2) Outpatient occupational therapy services as defined in § 410.59 of this chapter.

(3) Outpatient speech-language pathology services as defined in § 410.62 of this chapter.

Quality domain means the performance assessment category in which CMS assesses the IOTA participant's performance using a performance measure and quality measure set focused on improving the quality of transplant care as described in § 512.428.

Quality Health Information Network (QHIN) means a network of

organizations that agrees to common terms and conditions regarding data exchange with each other (a ''Common Agreement'') and to the functional and technical requirements for such data exchange (as specified in the QHIN Technical Framework or ''QTF'') under section 4003(b) of the 21st Century Cures Act (Pub. L. 114–255).

Quarterly attribution list means the quarterly CMS-generated attributed patient list that CMS provides to the IOTA participant in advance of each quarter during the model performance period in accordance with § 512.414(c)(ii)(2).

Resource gap analysis means the resources needed to implement the health equity plan interventions and identifies any gaps in the IOTA participant's current resources and the additional resources needed.

Response rate threshold means the level of complete and accurate reporting for each quality measure, within the quality measure set of the quality domain, that the IOTA participant must meet to earn points on the quality domain during a performance year as described in § 512.428(c) and (e).

Scientific Registry of Transplant Recipients or *SRTR* means the registry of information on transplant recipients established under section 373 of the Public Health Service Act.

Selected DSAs means those DSAs selected by CMS for purposes of selecting kidney transplant hospitals for participation in the IOTA Model.

Sharing arrangement means a financial arrangement to only share the upside risk payment and the downside risk payment lump-sum amount as set forth in § 512.452.

SNF stands for skilled nursing facility that meets sections all applicable sections of 1819 of the Act.

Survey and Reporting windows means the two distinct periods where IOTA participants are required to administer a quality measure-related survey or screening to attributed patients or submit patient responses on a quality measure to CMS as set forth in § 512.428(b)(2)(ii).

Target health disparities means health disparities experienced by one or more communities within the IOTA participant's population of attributed patients that the IOTA participant aims to reduce.

Targeted review process means the process in which an IOTA participant may dispute performance and payment calculations made, and issued, by CMS as set forth in § 512.34.

TGP means an entity that is enrolled in Medicare as a therapy group in private practice, includes at least one owner or employee who is a therapist in private practice, does not include an owner or employee who is a physician or nonphysician practitioner, and has a valid and active TIN.

Therapist means one of the following individuals as defined at § 484.4 of this chapter:

(1) Physical therapist.

(2) Occupational therapist.

(3) Speech-language pathologist.

Therapist in private practice means a therapist that complies with one of the following special provisions:

(1) For physical therapists in private practice in § 410.60(c) of this chapter.

(2) For occupational therapists in private practice in § 410.59(c) of this chapter.

(3) For speech-language pathologists in private practice in § 410.62(c) of this chapter.

Taxpayer identification number (TIN) means a Federal taxpayer identification number or employer identification number as defined by the Internal Revenue Service in 26 CFR 301.6109–1.

Transplant hospital means a hospital that furnishes organ transplants as defined in § 121.2 of this chapter.

Transplant physician means a physician who provides non-surgical care and treatment to transplant patients before and after transplant as defined in § 121.2 of this chapter.

Transplant program means a component within a transplant hospital which provides transplantation of a particular type of organ as defined in § 121.2 of this chapter.

Transplant recipient means a person who has received an organ transplant as defined in § 121.2 of this chapter.

Transplant target means the target number of kidney transplants calculated by CMS for the IOTA participant to measure the IOTA participant's performance in the achievement domain, as described in § 512.424.

Underserved communities mean populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life as defined by Executive Order 13985 of January 20, 2021.

Upside risk payment means the lump sum payment CMS makes to an IOTA participant if the IOTA participant's final performance score for a performance year falls within the payment range specified in § 512.430.

Waitlist means a list of transplant candidates, as defined in § 121.2 of this chapter, registered to the waiting list, as defined in § 121.2 of this chapter, maintained by a transplant hospital in accordance with § 482.94(b) of this chapter.

Increasing Organ Transplant Access Model Scope and Participation

§ 512.412 Participant eligibility and selection.

(a) *Participant eligibility.* A kidney transplant hospital is eligible to be selected as an IOTA participant, in accordance with the methodology described in paragraph (c) of this section, if the kidney transplant hospital meets both of the following criteria:

(1) The kidney transplant hospital annually performed 11 or more kidney transplants for patients aged 18 years or older, regardless of payer, each of the baseline years.

(2) The kidney transplant hospital annually performed more than 50 percent of its kidney transplants on patients 18 years of age or older each of the baseline years.

(b) *IOTA participant selection.* CMS uses the following process to select IOTA participants for inclusion in the model.

(1) *DSA stratification criteria.* CMS uses the following approach to stratify DSAs using the list of DSAs as of January 1, 2024:

(i) Census division of the DSA.

(ii) Total number of adult kidney transplants performed per year across eligible kidney transplant hospitals in the DSA during PY 1's baseline years.

(2) *DSA stratification process.* Prior to sampling DSAs, CMS uses the following steps to group DSAs into mutually exclusive groups.

(i) CMS assigns each DSA to one of the nine Census Divisions. CMS assigns each DSA to the Census Division where the majority of the DSA's population resides. CMS determines each DSA's population, and the share of a DSA's population in the applicable Census Division(s) using data from the 2020 Census.

(A) CMS assigns the Puerto Rico DSA to the South Atlantic Census Divisions.

(B) CMS combines the Middle Atlantic and New England Census Divisions and all DSAs therewithin creating eight groups of Census Divisions.

(ii) CMS identifies all kidney transplant hospitals located in each DSA within each Census Division group.

(iii) For each DSA within its assigned Census Division group, CMS identifies the eligible kidney transplant hospitals using the criteria specified in paragraph (a) of this section.

(iv) Using data from each of the baseline years for PY 1, CMS determines the average number of adult kidney

transplants performed annually by eligible transplant hospitals located in each DSA as follows:

(A) Sums the number of adult kidney transplants performed across eligible kidney transplant hospitals in a DSA during each of the baseline years for PY 1; and

(B) Divides each DSA's sum resulting from the calculation in paragraph (b)(2)(iv)(A) of this section by three to determine the amount the average number of adult kidney transplants furnished during the baseline years for PY 1.

(v) CMS separates DSAs in each Census Division group into two mutually exclusive groups of the same size, based on the average number of adult kidney transplants performed annually across the baseline years for PY 1, except where there are an odd number of DSAs within a Census Division group:

(A) DSAs with a higher number of adult kidney transplants per year across the baseline years for PY 1.

(B) DSAs with a lower number of adult kidney transplants per year across the baseline years for PY 1.

(vi) Where there are an odd number of DSAs within a Census Division group CMS uses the methodology set forth in paragraph (b)(3) of this section.

(3) *Random sampling of DSAs.* (i) For each DSA group within a Census Division group containing an odd number of DSAs, CMS randomly selects one DSA and determines its participation in the IOTA Model with a 50 percent probability.

(ii) CMS randomly samples, without replacement, 50 percent of the remaining DSAs in each group within each Census Division group created in paragraph (b)(2)(v) of this section.

(c) *Selection of IOTA participants in selected DSAs.* All eligible kidney transplant hospitals in the selected DSAs would be required to participate in the IOTA Model.

(d) CMS notifies IOTA participants of their selection to participate in the IOTA Model in a form and manner chosen by CMS at least 3 months prior to the start of the model performance period.

§ 512.414 Patient population.

(a) *General.* (1) CMS attributes kidney transplant waitlist patients and kidney transplant patients to IOTA participants based on the attribution criteria as described in paragraphs (b)(1) and (b)(2) of this section, for all of the following purposes:

(i) Sharing Medicare claims data for attributed beneficiaries with IOTA participants.

(ii) Assessing each IOTA participant's performance across the achievement domain, efficiency domain, and quality domain.

(iii) Determining performance-based payments to IOTA participants.

(2) Once a kidney transplant waitlist patient or kidney transplant patient is attributed to an IOTA participant, that respective patient may not opt out of attribution to an IOTA participant and remains attributed to the IOTA participant for the duration of the model performance period, unless the attributed patient meets the de-attribution criteria under paragraph (b)(3) of this section during annual attribution reconciliation as described in paragraph (b)(3) of this section.

(b) *Patient attribution and de-attribution criteria*—(1) *IOTA waitlist patient attribution.* (i) At the time CMS conducts attribution, as described in paragraph (c) of this section, if a kidney transplant waitlist patient meets the definition of an IOTA waitlist patient, as defined at § 512.402, CMS attributes the kidney transplant waitlist patient as an IOTA waitlist patient to an IOTA participant.

(2) *IOTA transplant patient attribution.* (i) At the time CMS conducts attribution, as described in paragraph (c) of this section, CMS attributes a kidney transplant patient as an IOTA transplant patient if the kidney transplant patient meets all of the following:

(A) The definition of an IOTA transplant patient, as defined at § 512.402.

(B) Is 18 years of age or older at the time of the patient's kidney transplant.

(C) Is alive.

(3) *De-attribution from an IOTA participant.* During annual attribution reconciliation, CMS uses the fourth quarter attribution list for each IOTA participant and de-attributes any attributed patients who, as of the last day of the PY being reconciled, meet any of the following de-attribution criteria:

(A) An IOTA waitlist patient was removed from and remains unregistered on an IOTA participant's kidney transplant waitlist.

(B) An IOTA waitlist patient that has died at any point during the PY.

(C) An IOTA transplant patient that has died at any point during the PY.

(D) An IOTA transplant patient who experiences transplant failure at any point during the model performance period and has not rejoined an IOTA participant's kidney transplant waitlist or received another transplant from an IOTA participant before the last day of the respective PY.

(c) *Attribution methodology.* CMS employs the following methodology to attribute kidney waitlist patients and kidney transplant patients to an IOTA participant after identifying all kidney waitlist patients and kidney transplant patients that meet the attribution criteria as specified in paragraphs (b)(1) and (b)(2) of this section:

(1) *Initial attribution.* (i) Prior to the model start date, CMS conducts initial attribution, as defined at § 512.402.

(ii) *Initial attribution list.* (A) CMS provides the initial attribution list to the IOTA participant no later than 15 days prior to the start of PY 1 and in a form and manner as determined by CMS.

(B) The initial attribution list includes a list of IOTA waitlist patients identified through initial attribution, effective-on the model start date.

(2) *Quarterly attribution.* (i) CMS conducts attribution, as defined at § 512.402, on a quarterly basis after the model start date, and updates the quarterly attribution list, as defined at § 512.402, for each IOTA participant, except in the event of termination in accordance with § 512.466.

(ii) *Quarterly attribution list.* CMS provides the quarterly attribution list, as defined at § 512.402, to the IOTA participant no later than 15 days prior to the start of each quarter and in a form and manner as determined by CMS. The quarterly attribution list includes, at minimum, all of the following:

(A) A list of all newly attributed patients, whose attribution to the IOTA participant becomes effective on the first day of the relevant upcoming quarter.

(B) A list of all attributed patients who continue to be attributed to the IOTA participant from the previous quarter.

(C) The dates in which attribution began, changed, or ended, where applicable for attributed patients.

(D) The attributed patient's data sharing preferences under § 512.440(b).

(3) *Annual attribution reconciliation.* (i) After the fourth quarter of each PY, CMS conducts annual attribution reconciliation as defined at § 512.402.

(ii) *Annual attribution reconciliation list.* CMS provides the annual reconciliation list to the IOTA participant before the second quarter of the following PY. Using the fourth quarter quarterly attribution list for each IOTA participant, the annual attribution reconciliation list identifies, at a minimum, all of the following, where applicable:

(A) A list of all attributed patients who remain attributed to the IOTA participant because they satisfied the

attribution criteria under §§ 512.414(1) and 512.414(2) for the respective PY.

(B) The dates in which attribution began, changed, or ended, where applicable.

(C) A list of all attributed patients who are de-attributed because they failed to satisfy the attribution criteria under § 512.414(x)(1) and (2).

(D) A list of all attributed patients who are de-attributed because they satisfy a de-attribution criterion under § 512.414(e)(4)(i).

(E) The dates on which each attributed patient satisfied a de-attribution criterion as specified under § 512.414(e)(4)(i).

(F) A list of the de-attribution criterion each attributed patient satisfied under § 512.414(e)(4)(i).

Performance Assessment and Scoring

§ 512.422 Overview of performance assessment and scoring.

(a) *General.* (1) CMS establishes the performances measures described in §§ 512.424, 512.426, and 512.428 to assess IOTA participants in the achievement domain, efficiency domain and quality domain.

(2) CMS assigns each set of metrics within a domain a point value with the total possible points awarded to an IOTA participant across the three domains equaling 100, as described in §§ 512.424, 512.426, and 512.428.

(b) *Data sources.* (1) CMS uses Medicare claims data and Medicare administrative data about beneficiaries, providers, suppliers, and data from the OPTN, to calculate performance for the IOTA participant based on the methodologies under §§ 512.424, 512.426, and 512.428.

(2) CMS may also use model-specific data reported by an IOTA participant to CMS under the IOTA Model to calculate IOTA participant performance in the domains.

§ 512.424 Achievement domain.

(a) *General.* (1) After each PY, CMS calculates the number of kidney transplants that each IOTA participant performed for the respective PY, in accordance with the provisions in paragraph (d) of this section.

(2) CMS compares the number of kidney transplants that an IOTA participant performed during the PY to the IOTA participant's transplant target, subject to a health equity performance adjustment as described in paragraph (e) of this section, for that PY, to determine the IOTA participant's score for the achievement domain.

(b) *Transplant target methodology.* CMS determines the IOTA participant's transplant target for each PY as follows:

(1) CMS analyzes the baseline years for the relevant PY and identifies:

(i) The highest annual number of deceased donor kidney transplants furnished by the IOTA participant to patients 18 years of age or older during a baseline year; and

(ii) The highest annual number of living donor kidney transplants furnished by the IOTA participant to patients 18 years of age or older during a baseline year.

(2) CMS sums the numbers in paragraphs (b)(1)(i) and (ii) of this section.

(3) *National growth rate calculation.* CMS calculates the national growth rate, as defined at § 512.402, using the baseline years for the relevant PY as follows:

(i) Subtracts the total number of kidney transplants furnished to patients 18 years of age or older during the second baseline from the total number of kidney transplants furnished to patients 18 years of age or older during the third baseline year.

(ii) Divides the amount resulting from the calculation in paragraph (b)(3)(i) of this section by the total number of kidney transplants furnished to patients 18 years of age or older during the third baseline year. The resulting amount is the national growth rate for the relevant PY.

(4) *Calculation of transplant target.* If the national growth rate calculated in paragraph (b)(3) of this section is—

(i) Positive, CMS multiples that national growth rate by the sum calculated in paragraph (b)(2) of this section. The resulting amount is an IOTA participants transplant target for the relevant PY; or

(ii) Negative, CMS does not multiply the national growth rate by the sum calculated in paragraph (b)(2) of this section. The IOTA participant's transplant target for the relevant PY is the sum calculated in paragraph (b)(2) of this section.

(c) *Notification of transplant target.* CMS notifies the IOTA participant of the transplant target by the first day of the start of each PY in a form and manner determined by CMS.

(d) *Calculation of kidney transplants performed during the PY.* (1)(i) After each PY, except as described in paragraph (d)(2) of this section, CMS counts the number of kidney transplants performed by the IOTA participant on patients who were 18 years of age or older at the time of transplant, during the PY.

(ii) CMS identifies kidney transplants performed by the IOTA participant using OPTN data, regardless of payer, and Medicare claims data.

(2) CMS counts each kidney transplant described in paragraph (d)(1) of this section as one transplant, except as described in paragraph (e) of this section.

(e) *Health equity performance adjustment.* (1) If a kidney transplant identified under paragraph (d) of this section was performed on a low-income population patient, CMS applies the health equity performance adjustment to that kidney transplant by multiplying each low-income population patient's kidney transplant by 1.2.

(2) CMS sums the number of kidney transplants identified under paragraph (d)(3) of this section and the number of kidney transplants adjusted by the health equity performance adjustment described in paragraph (e)(1) of this section to determine the total sum of kidney transplants performed by the IOTA participant in a PY.

(3) CMS uses the total sum of kidney transplants identified under paragraph (e)(2) of this section and determines the IOTA participant's achievement domain score in accordance with paragraph (f) of this section.

(f) *Achievement domain scoring.* For each PY, CMS awards the IOTA participant zero to 60 points for its performance in the achievement domain.

(1) CMS compares the total number of kidney transplants identified under paragraph (e)(2) of this section to the IOTA participant's transplant target, as described in paragraph (b) of this section.

(2) CMS uses the following scoring methodology to determine an IOTA participant's score on the achievement domain.

TABLE 1 TO PARAGRAPH (f)(2)—IOTA MODEL ACHIEVEMENT DOMAIN SCORING METHODOLOGY

Performance relative to transplant target	Lower bound condition	Upper bound condition	Points earned
150% of transplant target	Equals 150%	Greater than 150%	60
125% of transplant target	Equals 125%	Less than 150%	45
100% of transplant target	Equals 100%	Less than 125%	30

TABLE 1 TO PARAGRAPH (f)(2)—IOTA MODEL ACHIEVEMENT DOMAIN SCORING METHODOLOGY—Continued

Performance relative to transplant target	Lower bound condition	Upper bound condition	Points earned
75% of transplant target	Equals 75%	Less than 100%	15
75% of transplant target	N/A	Less than 75%	0

§ 512.426 Efficiency domain.

(a) *General.* For each PY, CMS assesses each IOTA participant on the metric described in paragraph (b) of this section to determine the IOTA participant's score for the efficiency domain.

(b) *Metric included in the efficiency domain.* For each PY, CMS assesses the IOTA participant on the following metric:

(1) *Organ-offer acceptance rate ratio.* For each PY, CMS calculates the organ-offer acceptance rate ratio by dividing the number of kidneys the IOTA participant accepted by the risk-adjusted number of expected organ-offer acceptances using SRTR's methodology as described in equation 1 to paragraph (b)(1).

Equation 1 to Paragraph (b)(1): Organ Offer Acceptance Rate Ratio

$$Organ\ Offer\ Acceptance\ Rate\ Ratio = \frac{Number\ of\ Acceptances + 2}{Number\ of\ Expected\ Acceptances + 2}$$

(i) CMS uses both of the following:

(A) SRTR data to calculate the organ-offer acceptance rate ratio.

(B) SRTR's adult kidney model strata risk-adjustment methodology and most available set of coefficients to calculate the number of expected organ-offer acceptances.

(ii) CMS includes all of the following kidney offers when calculating the organ-offer acceptance rate ratio for the IOTA participant:

(A) Offers that are ultimately accepted and transplanted.

(B) Offers to candidates on a single organ waitlist (except for Kidney/Pancreas candidates that are also listed for kidney alone).

(iii) CMS excludes the following kidney offers when calculating the organ-offer acceptance rate:

(A) Offers with multiple match runs from the same donor combined and duplicate offers.

(B) Offers with no match run acceptances.

(C) Offers that occurred after the last acceptance in a match run.

(D) Offers with a missing or bypassed response.

(E) Offers to multi-organ candidates (except for kidney/pancreas candidates that are also listed for kidney alone).

(c) *Efficiency domain scoring.* For each PY, CMS awards the IOTA participant 0 to 20 points for its performance in the efficiency domain.

(1) *General.* CMS determines the IOTA participant's score for the efficiency domain for each PY by taking the IOTA participant's score for the organ offer acceptance rate ratio, as described under paragraph (c)(2) of this section. This number is the IOTA participant's score for the efficiency domain for the PY.

(2) *Scoring for organ offer acceptance rate ratio.* CMS calculates the IOTA participant's achievement score, as described in paragraph (c)(2)(i) of this section, and improvement score, as described under paragraph (c)(2)(ii) of this section, for the organ offer acceptance rate ratio, compares the IOTA participant's achievement score and improvement score and awards to the IOTA participant the points that correspond to the higher score.

(i) *Achievement scoring.* CMS calculates the IOTA participant's achievement score based on the IOTA participant's performance on organ offer acceptance rate ratio ranking against a national target, including all eligible kidney transplant hospitals, using the scoring methodology described in table 1 to paragraph (c)(1)(i) of this section.

TABLE 1 TO PARAGRAPH (c)(1)(i)—IOTA MODEL ORGAN OFFER ACCEPTANCE RATE ACHIEVEMENT SCORING

Performance relative to national ranking	Lower bound condition	Upper bound condition	Points earned
80th Percentile relative to target OR for comparison.	Equals 80th percentile	Greater than 80th percentile	20
60th Percentile	Equals 60th percentile	Less than 80th percentile	15
40th Percentile	Equals 40th percentile	Less than 60th percentile	10
20th Percentile	Equals 20th percentile	Less than 40th percentile	6
20th Percentile	N/A	Less than 20th percentile	0

(ii) *Improvement scoring.* CMS compares the IOTA participant's organ offer acceptance rate ratio during the PY, calculated as described under paragraph (c)(1)(i) of this section, to the IOTA participant's improvement benchmark rate, calculated as described under paragraph (c)(1)(ii)(A) of this section.

(A) *Improvement benchmark rate.* CMS calculates an improvement benchmark rate for the IOTA participant. To determine an IOTA participant's improvement benchmark rate for a given PY, CMS multiplies an IOTA participant's organ offer acceptance rate ratio during the third baseline year by 120 percent.

(B) *Improvement score calculation.* For each PY, CMS uses the following methodology to determine each IOTA participant's improvement score on the organ offer acceptance rate ratio:

(*1*) If the IOTA participant's organ-offer acceptance rate ratio is greater than or equal to the improvement benchmark rate, CMS awards the IOTA participant 12 points in the efficiency domain.

(*2*) If the IOTA participant's organ offer acceptance rate ratio is equal to or less than the IOTA participant's organ-offer acceptance rate ratio in the third baseline year for that respective PY, CMS awards the IOTA participant 0 points in the efficiency domain.

(*3*) If the IOTA participant's organ offer acceptance rate ratio is greater than the IOTA participant's organ-offer acceptance rate ratio in the third baseline year for that respective PY but less than the improvement benchmark rate, CMS uses the following equation:

Equation 1 to Paragraph (c)(1)(ii)(B)(1): IOTA Model Organ Offer Acceptance Rate Ratio Improvement Scoring Equation

$$12\,x\frac{Rate\ Earned\ in\ Performance\ Year\ -Third\ Baseline\ Year\ Rate}{Improvment\ Benchmark\ Rate-Third\ Baseline\ Year\ Rate}$$

§ 512.428 Quality domain.

(a) *General.* For each PY, CMS assesses each IOTA participant on the metrics described under paragraphs (b)(1) and (2) of this section to determine the IOTA participant's quality domain score, as described under paragraphs (c) through (e) of this section, for the quality domain.

(b) *Metrics included in the quality domain.* For each PY, CMS assesses each IOTA participant using the following quality metrics:

(1) *Post-transplant graft survival.* For each PY, CMS calculates an IOTA participant's composite graft survival rate by dividing the cumulative number of all functioning kidney grafts for the IOTA participant's IOTA transplant patients by the cumulative number of all kidney transplants performed by the IOTA participant during the first PY and all subsequent PYs on patients 18 years or older at the time of the transplant, as described in Equation 1 to Paragraph (b)(1).

Equation 1 to Paragraph (b)(1): Composite Graft Survival Rate

$$Composite\ Graft\ Survival\ Rate\ =\frac{\#\ of\ Functioning\ Grafts}{\#\ of\ Completed\ Kidney\ Transplants}$$

(i) For the first PY, CMS calculates the IOTA participant's composite graft survival rate based solely on the number of functioning grafts furnished to IOTA transplant patients during that PY and the number of completed kidney transplants during that PY, as described in paragraph (b)(1) of section.

(ii) For all subsequent PYs, CMS calculates the IOTA participant's cumulative composite graft survival rate using the same calculation methodology described in paragraph (b)(1) of this section.

(iii) CMS excludes the following from the numerator when calculating the composite graft survival rate:

(A) Graft failure, based on OPTN adult kidney transplant recipient follow-up forms for all completed kidney transplants to determine failed grafts as defined by SRTR.

(B) Re-transplant.

(C) Death.

(D) Patients who are under the age of 18 years of age at the time of the kidney transplant.

(E) Offers to multi-organ candidates (except for kidney/pancreas candidates that are also listed for kidney alone).

(iv)(A) When calculating the composite graft survival rate, CMS only includes kidney transplants for patients who are 18 years of age and older at the time of the kidney transplant in the number of kidney transplants performed by the IOTA participant during each PY in the denominator.

(B) CMS identifies kidney transplants performed by the IOTA participant using OPTN data, regardless of payer, and Medicare claims data.

(2) *Quality measure set.* (i) *General.* For each PY, CMS assesses the IOTA participant's performance on the following quality measures:

(A) CollaboRATE Shared Decision-Making Score (CollaboRATE) (CBE ID:3327).

(B) Colorectal Cancer Screening (COL) (CBE ID: 0034).

(C) 3-Item Care Transition Measure (CTM–3) (CBE ID: 0228).

(ii) *Quality measure set survey and reporting requirements.* (A) *General.* For each PY:

(*1*) IOTA participants must survey, where applicable, attributed patients and submit data for the quality measures specified in paragraph (b)(2)(ii)(B) and (C) of this section to CMS during survey and reporting windows in a form and manner and at times established by CMS.

(*2*) CMS notifies IOTA participants of the survey and reporting windows for each quality measure specified in paragraphs (b)(2)(ii)(B) and (C) of this section by the first day of each PY in a form and manner determined by CMS.

(B) *PRO–PM Survey and data reporting requirements.* The IOTA participant must survey and submit data for all attributed patients once a PY, at minimum, on all of the following quality measures in accordance with paragraph (b)(2)(ii)(A) of this section:

(*1*) CollaboRATE.

(*2*) CTM–3

(C) *Process measure survey and data reporting requirements.* The IOTA Participant must administer the COL measure yearly to all IOTA transplant patients who are Medicare beneficiaries.

(3) *Quality measure set selection under the IOTA Model.* (i) *General.* CMS selects quality measures for inclusion in the IOTA Model quality measure set for the purpose of assessing IOTA participant performance in the quality domain.

(ii) *Updating of measure specifications.* CMS uses rulemaking to make substantiative updates to the specifications of the quality measures used in the IOTA Model.

(iii) *Measure retention.* All quality measures selected under paragraph (b)(2)(i) of this section will remain in the quality measure set unless CMS, through rulemaking, removes or replaces them.

(iv) *Measure addition, removal, suspension, or replacement through the rulemaking process.* CMS will use the rulemaking process to add, remove, suspend, or replace quality measures in the IOTA Model to allow for public comment unless a quality measure raises specific safety concerns.

(v) *Factors for consideration of removal of quality measures.* CMS weighs whether to remove a measure from the quality measure set specified in paragraph (b)(2)(i) of this section

based on one or more of the following factors:

(A) A quality measure does not align with current clinical guidelines or practice.

(B) Performance on a quality measure among IOTA participants is so high and unvarying that meaningful distinctions and improvement in performance can no longer be made (''topped out'' measure), as defined in 42 CFR 412.140(g)(3)(i)(A).

(C) Performance or improvement on a quality measure does not result in better patient outcomes.

(D) The availability of a more broadly applicable quality measure (across settings or populations) or the availability of a quality measure that is more proximal in time to desired patient outcomes for the particular topic.

(E) The availability of a quality measure that is more strongly associated with desired patient outcomes for the particular topic.

(F) Collection or public reporting of a quality measure leads to negative unintended consequences other than patient harm.

(G) It is not feasible to implement the quality measure specifications.

(H) The costs associated with a quality measure outweigh the benefit of its continued use in the IOTA Model.

(vi) *Application of measure removal factors.* CMS assesses the benefits of removing or replacing a quality measure from the IOTA Model on a case-by-case basis.

(vii) *Patient safety exception.* (A) If CMS determines that the continued requirement for IOTA participants to submit data on a quality measure raises specific patient safety concerns, CMS may elect to immediately remove the quality measure from the IOTA Model quality measure set.

(B) CMS, upon removal of a quality measure and in a form and manner determined by CMS, does both of the following:

(*1*) Provide notice to IOTA participants and the public at the time CMS removes the quality measure, along with a statement of the specific patient safety concerns that would be raised if IOTA participants continued to submit data on the quality measure.

(*2*) Provide notice of the removal in the **Federal Register**.

(c) *Quality domain scoring.* For each PY, CMS awards the IOTA participant zero to 20 points for the IOTA participant's performance in the quality domain, in accordance with the following:

(1) For composite graft survival rate, as described under paragraph (d) of this section, the IOTA participant may receive up to 10 points.

(2) For the quality measure set, as described under paragraph (e) of this section, the IOTA participant may receive up to 10 points.

(i) The IOTA participant may receive a maximum of 4 points for their performance on the CollaboRATE Shared Decision-Making Score.

(ii) The IOTA participant may receive a maximum of 2 points for their performance on the Colorectal Cancer Screening (COL) measure.

(iii) The IOTA participant may receive a maximum of 4 points on the 3-Item Care Transition Measure (CTM–3).

(d) *Composite graft survival rate scoring.* CMS awards points to the IOTA participant based on the IOTA participant's performance on the composite graft survival rate, as described in paragraph (b)(1) of this section, ranked against a national target, inclusive of all eligible transplant hospitals. CMS awards points to the IOTA participant for composite graft survival rate as described in Table 1 to paragraph (d) of this section:

TABLE 1 TO PARAGRAPH (d)—IOTA MODEL COMPOSITE GRAFT SURVIVAL RATE SCORING

Performance relative to target	Lower bound condition	Upper bound condition	Points earned
80th Percentile	Equals 80th percentile	Greater than 80th percentile	10
60th Percentile	Equals 60th percentile	Less than 80th percentile	8
40th Percentile	Equals 40th percentile	Less than 60th percentile	5
20th Percentile	Equals 20th percentile	Less than 40th percentile	3
20th Percentile	N/A	Less than 20th percentile	0

(e) *Quality measure set scoring.* (1) For the first two PYs, CMS awards a maximum of 10 points to an IOTA participant, based on an IOTA participant's performance on the quality measures and requirements under paragraph (b)(2) of this section, as follows:

(i) *Response rate threshold:* For the first two PYs CMS assesses an IOTA participant's performance on quality measures and awards points based on a response rate threshold for each measure.

(A) CMS defines the response rate threshold at the level of complete and accurate reporting for each quality measure specified under paragraph (b)(2)(i) of this section.

(B) CMS determines the response rate threshold for each measure before the start of each PY.

(C) CMS informs IOTA participants of the response rate threshold for each quality measure by the first day of the PY in a form and manner chosen by CMS.

(ii) *Quality measure set scoring methodology.* CMS uses the scoring methodology described in Table 1 to paragraph (e)(1) of this section to determine the following:

(A) The IOTA participant's score on the CollaboRATE;

(B) The IOTA participant's score on the CTM–3; and

(C) The IOTA participant's score on the COL measure for all IOTA transplant patients who are Medicare beneficiaries.

TABLE 1 TO PARAGRAPH (e)(1)—IOTA MODEL QUALITY MEASURE SET SCORING

Measure	Performance relative to target	Lower bound condition	Upper bound condition	Points earned
CollaboRATE/CTM–3	90% Response Rate	Equals 90%	Greater than 90%	4
CollaboRATE/CTM–3	50% Response Rate	Equals 50%	Less than 90%	2
CollaboRATE/CTM–3	50% Response Rate	N/A	Less than 50%	0
COL	50% Response Rate	Equals 50%	Greater than 50%	2
COL	50% Response Rate	N/A	Less than 50%	0

(2) For subsequent PYs—

(i) The quality performance score will be phased in such that an IOTA participant must continue to report all measures, but CMS assesses an IOTA participant's performance based on quality performance benchmarks and response rate thresholds, as specified by CMS in future rulemaking, for each quality measure under § 512.428(b)(2); and

(ii) CMS awards a maximum of 10 points to an IOTA participant based on its performance as set forth in paragraph (e)(2)(i) of this section.

Payment

§ 512.430 Upside risk payment, downside risk payment, and neutral zone.

(a) *General.* CMS determines if an IOTA participant qualifies for an upside risk, downside risk payment, or neutral zone for each PY based on the IOTA participant's final performance score, in accordance with paragraphs (b)(1) through (3) of this section.

(b) *Upside risk payment, neutral zone, and downside risk payment calculation methodology*—(1) *Upside risk payment calculation methodology.* If in PYs 1–6 the IOTA participant's final performance score is 60 points or above, CMS calculates the IOTA participant's upside risk payment as follows:

(i) Subtracts 60 from the IOTA participant's final performance score from 100.

(ii) Divides the amount resulting from the calculation in paragraph (b)(1)(i) of this section by 40.

(iii) Multiplies the amount resulting from the calculation in paragraph (b)(1)(ii) of this section by $8,000.

(iv) Multiplies the amount resulting from the calculation in paragraph (b)(1)(iii) of this section by the total number of Medicare kidney transplants performed by the IOTA participant during the PY.

(2) *Neutral zone.* (i) For PY 1, IOTA participants with a final performance score below 60 points qualify for the neutral zone and neither owes a downside risk payment to CMS nor receives an upside risk payment from CMS.

(ii) For PYs 2–6, if an IOTA participant's final performance is between 41 to 59 points (inclusive), the IOTA participant qualifies for the neutral zone.

(3) *Downside risk payment calculation methodology.* If an IOTA participant is at or below 40 points in PYs 1–6, the IOTA participant qualifies for a downside risk payment. The downside risk payment is calculated as follows:

(i) For PY 1, this paragraph does not apply, and the IOTA participant does not owe a downside risk payment to CMS.

(ii) For PYs 2–6, CMS calculates the IOTA participant's downside risk payment as follows:

(A) Subtracts the IOTA participant's final performance score from 40.

(B) Divides the amount resulting from the calculation in paragraph (b)(3)(ii)(A) of this section by 40.

(C) Multiplies the amount resulting from the calculation in paragraph (b)(3)(ii)(B) of this section by $2,000.

(D) Multiplies the amount resulting from the calculation in paragraph (b)(3)(ii)(C) of this section by the total number of Medicare kidney transplants performed by the IOTA participant during the PY to calculate the amount of the IOTA participant's downside risk payment.

(d) *Upside risk payment and downside risk payment timeline.* (1) CMS conducts and calculates preliminary performance assessment and payment calculations at least 3 to 6 months after the end of each PY.

(2) CMS notifies the IOTA participant of their preliminary performance assessment and payment calculations in a form and manner determined by CMS at least 5 to 9 months after the end of each PY.

(3) CMS gives IOTA participants 30 days to review preliminary performance assessment and payment calculations and request targeted reviews under § 512.434.

(4) CMS notifies the IOTA participant of their final performance score and any associated upside risk payment or downside risk payment at least 30 days after notifying the IOTA participant of their preliminary performance assessment and payment calculations.

(5) *Upside risk payment.* After CMS notifies the IOTA participant of their final performance score and any associated upside risk payment, and by a date determined by CMS, CMS issues the upside risk payment to the tax identification number (TIN) on file for the IOTA participant in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS).

(6) *Downside risk payment.* After CMS notifies the IOTA participant of their final performance score and any associated downside risk payment and by a date determined by CMS, CMS issues a demand letter to the TIN on file for the IOTA participant in PECOS for any downside risk payment owed to CMS.

(i) CMS includes all of the following details in the demand letter:

(A) IOTA participant performance in the model.

(B) Amount of downside risk payment owed to CMS by the IOTA participant.

(C) How the IOTA participant may make payments to CMS.

(ii) The IOTA participant must pay the downside risk payment to CMS in a single payment at least 60 days after the date which the demand letter is issued.

§ 512.434 Targeted review.

(a) *General.* Subject to the limitations on review in subpart c of this part, an IOTA participant may submit a targeted review request for one or more calculations made, and issued by, CMS within the preliminary performance assessment and payment calculations, if either of the following occur:

(1) The IOTA participant believes an error occurred in calculations due to data quality or other issues.

(2) The IOTA participant believes an error occurred in calculations due to misapplication of methodology.

(b) *Requirements.* The request must satisfy the following criteria:

(1) Be submitted within 30 days, or another time period as specified by CMS, of receiving its preliminary performance assessment and payment calculations from CMS.

(2) Include supporting information in a form and manner as specified by CMS.

(c) *Limitations on review.* (1) CMS does not consider a targeted review request any policy or methodology, including without limitation the following:

(i) The selection of the kidney transplant hospital to be an IOTA participant.

(ii) The attribution of IOTA waitlist patients and the attribution of IOTA transplant patients to the IOTA participant, or to any other kidney transplant hospital selected for participation in the IOTA Model, or to any kidney transplant hospital not selected for participation in the IOTA Model.

(iii) The methodology used for determining the achievement domain, efficiency domain, and quality domain.

(iv) The methodology used for calculating and assigning points for each metric within the achievement domain, efficiency domain, and quality domain.

(v) The methodology used for calculating the payment amount per Medicare kidney transplant paid to an IOTA participant.

(2) CMS may review a targeted review request that includes one or more of the limitations in paragraph (c)(1) of this section, provided that all remaining

considerations of the request meet all other criteria for consideration by CMS in this section.

(d) *Targeted review process.* The IOTA participant must submit a request for targeted review in accordance with paragraphs (a) through (c) of this section. The process for a targeted review is as follows:

(1) *Initial and final assessments.* Upon receipt of a targeted review request from an IOTA participant CMS conducts an initial and final assessment as follows:

(i) *Initial assessment.* (A) CMS determines if the targeted review request meets the targeted review requirements in paragraph (b) of this section and contains sufficient information to substantiate the request.

(B) If the request is not compliant with paragraphs (a) through (c) of this section or requires additional information:

(*1*) CMS follows up with the IOTA participant to request additional information in a form and manner as specified by CMS.

(*2*) The IOTA participant must respond within 30 days of CMS's request for additional information in a form and manner as specified by CMS.

(*3*) An IOTA participant's non-responsiveness to the request for additional information from CMS may result in the closure of the targeted review request.

(ii) *Final assessment.* (A) Upon completion of an initial assessment, as described in paragraph (d)(1)(i) of this section, CMS determines whether it erred in calculation, as disputed by the IOTA participant.

(B) If a calculation error is found as a result of an IOTA participant's targeted review request—

(*1*) CMS—(*i*) Notifies the IOTA participant within 30 days of any findings in a form and manner as specified by CMS; and

(*ii*) Resolves and correct any resulting error or discrepancy in the amount of the upside risk payment or downside risk payment in a time and manner as determined by CMS.

(*2*) CMS' correction of any error or discrepancy may delay the effective date of an IOTA participant's upside risk payments or downside risk payments.

(2) Targeted review decisions made by CMS are final, unless submitted for administrative review as described in § 512.190.

§ 512.436 Extreme and uncontrollable circumstances.

(a) *General.* CMS—

(1) Applies determinations made under the Quality Payment Program with respect to whether an extreme and uncontrollable circumstance has occurred and the affected area during the PY; and

(2) Has sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred and the percentage of attributed patients residing in affected areas.

(b) *Downside risk payment.* In the event of an extreme and uncontrollable circumstance, as determined by the Quality Payment Program, CMS may reduce the amount of the IOTA participant's downside risk payment, if applicable, prior to recoupment. CMS determines the amount of the reduction by multiplying the downside risk payment by both the following:

(1) The percentage of total months during the PY affected by the extreme and uncontrollable circumstance.

(2) The percentage of attributed patients who reside in an area affected by the extreme and uncontrollable circumstance.

Data Sharing

§ 512.440 Data sharing.

(a) *General.* CMS shares certain beneficiary-identifiable data as described in paragraph (b) of this section and certain aggregate data as described in paragraph (c) of this section with IOTA participants regarding attributed patients including attributed patients who are Medicare beneficiaries and performance under the model.

(b) *Beneficiary-identifiable data.* CMS shares beneficiary-identifiable data with IOTA participants as follows:

(1) CMS makes available certain beneficiary-identifiable data described in paragraphs (b)(4) and (5) of this section for IOTA participants to request for purposes of conducting health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of their attributed patients who are Medicare beneficiaries.

(2) An IOTA participant that wishes to receive beneficiary-identifiable data for its attributed patients who are Medicare beneficiaries must do all of the following:

(i) Submit a formal request for the data, on an annual basis in a manner and form and by a date specified by CMS, which identifies the data being requested and attests that—

(A) The IOTA participant is requesting this beneficiary-identifiable data as a HIPAA covered entity or as a business associate, as those terms are defined at 45 CFR 160.103, to the IOTA participant's providers and suppliers who are HIPAA covered entities; and

(B) The IOTA participant's request reflects the minimum data necessary, as set forth in paragraph (b)(6) of this section, for the IOTA participant to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501;

(ii) Limit the request to Medicare beneficiaries whose name appears on the quarterly attribution list who have been notified in compliance with § 512.450 that the IOTA participant has requested access to beneficiary-identifiable data, and who did not decline having their claims data shared with the IOTA participant as provided in paragraph (b)(7) of this section; and

(iii) Sign and submit a data sharing agreement with CMS as set forth in paragraph (b)(8) of this section.

(3) CMS share beneficiary-identifiable data with an IOTA participant on the condition that the IOTA participant, its IOTA collaborators, and other individuals or entities performing functions or services related to the IOTA participant's activities observe all relevant statutory and regulatory provisions regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information and comply with the terms of the data sharing agreement described in paragraph (b)(8) of this section.

(4) CMS omits from the beneficiary-identifiable data any information that is subject to the regulations in 42 CFR part 2 governing the confidentiality of substance use disorder patient records.

(5) The beneficiary-identifiable data will include, when available, the following information:

(i) *Quarterly attribution lists.* For the relevant PY, CMS shares with the IOTA participant the quarterly attribution lists, which will include but may not be limited to the following information for each attributed patient:

(A) The year that CMS attributed the patient to the IOTA participant.

(B) The effective date of the patient's attribution to the IOTA participant.

(C) The effective date of the patient's de-attribution from the IOTA participant and the reason for such removal (if applicable).

(D) For Medicare beneficiaries, the attributed patient's data sharing preference.

(ii) *Beneficiary-identifiable claims data.* CMS makes available certain beneficiary-identifiable claims data for retrieval by IOTA participants no later than 1 month after the start of each PY,

in a form and manner specified by CMS. IOTA participants may retrieve the following data at any point during the relevant PY. This claims data includes all of the following:

(A) Three years of historical Parts A, B, and D claims data files from the 36 months immediately preceding the effective date of each attributed patient who is a Medicare beneficiary's attribution to the IOTA participant.

(B) Monthly Parts A, B, and D claims data files for attributed patients who are Medicare beneficiaries.

(C) Monthly Parts A, B, and D claims data files for Medicare beneficiaries who have been de-attributed from the IOTA participant for claims with a date of service before the date the Medicare beneficiary was de-attributed from the IOTA participant.

(6) The IOTA participant must limit its attributed Medicare beneficiary identifiable data requests to the minimum necessary to accomplish a permitted use of the data.

(i) The minimum necessary Parts A and B data elements may include but are not limited to the following data elements:

(A) Medicare beneficiary identifier (ID).

(B) Procedure code.

(C) Gender.

(D) Diagnosis code.

(E) Claim ID.

(F) The from and through dates of service.

(G) The provider or supplier ID.

(H) The claim payment type.

(I) Date of birth and death, if applicable.

(J) Tax identification number (TIN).

(K) National provider identifier (NPI).

(ii) The minimum necessary Part D data elements may include but are not limited to the following data elements:

(A) Beneficiary ID.

(B) Prescriber ID.

(C) Drug service date.

(D) Drug product service ID.

(E) Quantity dispensed.

(F) Days supplied.

(G) Brand name.

(H) Generic name.

(I) Drug strength.

(J) TIN.

(K) NPI.

(L) Indication if on formulary.

(M) Gross drug cost.

(7)(i)(A) IOTA participants must send Medicare beneficiaries a notification about the IOTA model and the opportunity to decline claims data sharing as required under § 512.450.

(B) Such notifications must state that the IOTA participant may have requested beneficiary-identifiable claims data about the Medicare beneficiary for purposes of its care coordination, quality improvement work, and population-based activities relating to improving health or reducing health care costs, and inform the Medicare beneficiary how to decline having his or her claims information shared with the IOTA participant in the form and manner specified by CMS.

(ii) Medicare beneficiary requests to decline claims data sharing remain in effect unless and until a beneficiary subsequently contacts CMS to amend that request to permit claims data sharing with IOTA participants.

(iii) The opportunity to decline having claims data shared with an IOTA participant under paragraph (b)(7)(i) of this section does not apply to:

(A) The aggregate data that CMS provides to IOTA participants under paragraph (c) of this section.

(B) The initial attribution lists that CMS provides to IOTA participants as defined at § 512.402 and under § 512.414(c)(1)(ii).

(C) The quarterly attribution lists that CMS provides to IOTA participants as defined at § 512.402 and under § 512.414(c)(2)(ii).

(D) The annual attribution reconciliation list that CMS provides to IOTA participants as defined at § 512.402 and under § 512.414(c)(3)(ii).

(8)(i) If an IOTA participant wishes to retrieve any beneficiary-identifiable data specified in paragraph (b) of this section, the IOTA participant must complete and submit, on an annual basis, a signed data sharing agreement, to be provided in a form and manner specified by CMS, under which the IOTA participant agrees to all of the following:

(A) To comply with the requirements for use and disclosure of this beneficiary-identifiable data that are imposed on covered entities by the HIPAA regulations at 45 CFR part 160 and part 164, subparts A and E, and the requirements of the IOTA model set forth in this part.

(B) To comply with additional privacy, security, breach notification, and data retention requirements specified by CMS in the data sharing agreement.

(C) To contractually bind each downstream recipient of the beneficiary-identifiable data that is a business associate of the IOTA participant, including all IOTA collaborators, to the same terms and conditions to which the IOTA participant is itself bound in its data sharing agreement with CMS as a condition of the business associate's receipt of the beneficiary-identifiable data retrieved by the IOTA participant under the IOTA model.

(D) That if the IOTA participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the data sharing agreement, CMS may:

(*1*) Deem the IOTA participant ineligible to retrieve the beneficiary-identifiable data under paragraph (b) of this section for any amount of time;

(*2*) Terminate the IOTA participant's participation in the IOTA model under § 512.466; and

(*3*) Subject the IOTA participant to additional sanctions and penalties available under the law.

(ii) An IOTA participant must comply with all applicable laws and the terms of the data sharing in order to retrieve beneficiary-identifiable data.

(c) *Aggregate Data.* (1) CMS shares aggregate performance data with IOTA participants, in a form and manner to be specified by CMS, which has been de-identified in accordance with 45 CFR 164.514(b). This aggregate data includes, when available, certain de-identified data detailing the IOTA participant's performance against the transplant target information for each PY.

§ 512.442 Transparency requirements.

(a) *Publication of transplant patient selection criteria.* The IOTA participant must publicly post on its website, the criteria used by the IOTA participant for evaluating and selecting patients for addition to their kidney transplant waitlist by the end of PY 1.

(b) *Transparency into kidney transplant organ offers.* The IOTA participant must do the following for all IOTA waitlist patients who are Medicare beneficiaries during the model performance period:

(1) Inform IOTA waitlist patients who are Medicare beneficiaries of the number of times an organ is declined on the patient's behalf.

(i) For months in which an organ offer is made, provide notices to each IOTA waitlist patient who is a Medicare beneficiary on a monthly basis that include the following:

(A) The number of times an organ is declined on the IOTA waitlist patient's behalf.

(B) The reason(s) why the organ was declined.

(2) Record in the IOTA waitlist patient's medical record that the patient—

(i) Received the information specified in paragraph (b)(1) of this section; and

(ii) The method by which information was delivered.

(3) Share the information specified in paragraph (b)(1) of this section with the

IOTA waitlist patient's nephrologist or nephrology professional if deemed appropriate by the IOTA participant.

(c) *Review of selection criteria and organ-offer filters.* IOTA participants must review transplant acceptance criteria and organ offer filters with their IOTA waitlist patients who are Medicare beneficiaries at least once every 6 months that the Medicare beneficiary is on their waitlist.

(1) The IOTA participant must conduct this review via patient visit, phone, email or mail on an individual basis, unless the Medicare beneficiary declines this review.

(2) [Reserved]

§ 512.444 Health equity plans.

(a) For PY 2 through PY 6, each IOTA participant must submit a health equity plan, by a date and in a form and manner determined by CMS, that meets the following requirements:

(1) Identifies target health disparities.

(2) Identifies the data sources used to inform the identification of target health disparities.

(3) Describes the health equity plan intervention.

(4) Includes a resource gap analysis.

(5) Includes a health equity project plan.

(6) Identifies health equity plan performance measure(s).

(7) Identifies health equity goals and describes how the IOTA participant will use the health equity goals to monitor and evaluate progress in reducing targeted health disparities

(b) Once the IOTA participant submits their health equity plan to CMS, CMS uses reasonable efforts to approve or reject the health equity plan within 60 business days.

(c) If CMS approves the IOTA participant's health equity plan, the IOTA participant must engage in activities related to the execution of the IOTA participant's health equity plan, including implementing health equity plan interventions and monitoring and evaluating progress in reducing target health disparities.

(d) If CMS determines that the IOTA participant's health equity plan does not satisfy the requirements and is inconsistent with the applicable CMS Health Equity Plan guidance, does not provide sufficient evidence or documentation to demonstrate that the health equity plan is likely to accomplish the IOTA participant's intended health equity goals, or is likely to result in program integrity concerns, or negatively impact beneficiaries' access to quality care, CMS may reject the health equity plan or require amendment of the health equity plan at any time, including after its initial submission and approval.

(1) If CMS rejects the IOTA participant's health equity plan, in whole or in part, the IOTA participant may not, and must require its IOTA collaborators to not, conduct health equity activities identified in the health equity plan.

(2) [Reserved]

(e) In PY 3, and each subsequent PY, in a form and manner and by the date(s) specified by CMS, the IOTA participant must submit to CMS an update on its progress in implementing its health equity plan. This update must include all of the following:

(1) Updated outcomes data for the health equity plan performance measure(s).

(2) Updates to the resource gap analysis.

(3) Updates to the health equity project plan.

(f) If the IOTA participant fails to meet the requirements described in paragraph (a) of this section, CMS may subject the IOTA participant to remedial action, as specified in § 512.464, including either of the following:

(1) Corrective action such as recoupment of any upside risk payments.

(2) Termination from the model.

Beneficiary Protections, Financial Arrangements, Beneficiary Incentives, and Compliance

§ 512.450 Required beneficiary notifications.

(a) *General.* (1) IOTA participants must provide notice to attributed patients that they are participating in the IOTA Model.

(2) CMS provides a notification template that IOTA participants must use. The template, at minimum does all of the following:

(i) Indicates content that the IOTA participant must not change.

(ii) Indicates where the IOTA participant may insert its own content.

(iii) Includes information regarding the attributed patient's opportunity to opt-out of data sharing with IOTA participants and how they may opt out if they choose to do so.

(3) To notify attributed patients of their rights and protections and that the IOTA participant is participating in the IOTA Model the IOTA participant must do all of the following:

(i) Prominently display informational materials in each of their office or facility locations where attributed patients receive treatment.

(ii) Include in a clear manner on its public facing website, and to each attributed patient in a paper format.

(iii) Provide this notification to each attributed patient in a paper format.

(b) *Applicability of general Innovation Center model provisions.* (1) The requirement described in § 512.120(c) do not apply to the CMS-provided materials described in paragraph (a) of this section.

(2) All other IOTA participant communications that are descriptive model materials and activities as defined under § 512.110 must meet the requirements described in § 512.120(c).

§ 512.452 Financial sharing arrangements and attributed patient engagement incentives.

(a) *General.* (1) The IOTA participant—

(i) May enter into a sharing arrangement with an IOTA collaborator to make a gainsharing payment, or to receive an alignment payment, or both; and

(ii) Must not make a gainsharing payment or receive an alignment payment except in accordance with a sharing arrangement.

(2) A sharing arrangement must comply with the provisions of this section and all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.

(3) The IOTA participant must develop, maintain, and use a set of written policies for selecting providers and suppliers to be IOTA collaborators.

(i) The selection criteria must include the quality of care delivered by the potential IOTA collaborator.

(ii) The selection criteria cannot be based directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among any of the following:

(A) The IOTA participant.

(B) Any IOTA collaborator.

(C) Any collaboration agent.

(D) Any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent.

(iii) The written policies must contain criteria related to, and inclusive of, the anticipated contribution to performance across the achievement domain, efficiency domain, and quality domain by the potential IOTA collaborator.

(4) The board or other governing body of the IOTA participant must have responsibility for overseeing the IOTA participant's participation in the IOTA Model, including but not limited to all of the following:

(i) Arrangements with IOTA collaborators.

(ii) Payment of gainsharing payments.

(iii) Receipt of alignment payments.

(iv) Use of beneficiary incentives in the IOTA Model.

(5) If an IOTA participant enters into a sharing arrangement, its compliance program must include oversight of sharing arrangements and compliance with the applicable requirements of the IOTA Model.

(b) *Requirements.* (1) A sharing arrangement must be—

(i) In writing;

(ii) Signed by the parties; and

(iii) Entered into before care is furnished to attributed patient during the PY under the sharing arrangement.

(2) Participation in a sharing arrangement must be voluntary and without penalty for nonparticipation.

(3) Participation in the sharing arrangement must require the IOTA collaborator to comply with the requirements of this model, as those pertain to their actions and obligations.

(4) The sharing arrangement—

(i) Must set out the mutually agreeable terms for the financial arrangement between the parties to guide and reward model care redesign for future performance across the achievement domain, efficiency domain, and quality domain;

(ii) Must not reflect the results of model PYs that have already occurred; and

(iii) Where the financial outcome of the sharing arrangement terms are known before signing.

(5) The sharing arrangement must require the IOTA collaborator and its employees, contractors (including collaboration agents), and subcontractors to comply with all of the following:

(i) The applicable provisions of this part (including requirements regarding beneficiary notifications, access to records, record retention, and participation in any evaluation, monitoring, compliance, and enforcement activities performed by CMS or its designees).

(ii) All applicable Medicare provider enrollment requirements at § 424.500 *et seq.* of this chapter, including having a valid and active TIN or NPI, during the term of the sharing arrangement.

(iii) All other applicable laws and regulations.

(5) The sharing arrangement must require the IOTA collaborator to have or be covered by a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the IOTA Model that apply to its role as an IOTA collaborator, including any distribution arrangements.

(6) The sharing arrangement must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care.

(7) The written agreement memorializing a sharing arrangement must specify all of the following:

(i) The purpose and scope of the sharing arrangement.

(ii) The identities and obligations of the parties, including specified IOTA activities and other services to be performed by the parties under the sharing arrangement.

(iii) The date of the sharing arrangement.

(iv) Management and staffing information, including type of personnel or contractors that would be primarily responsible for carrying out IOTA activities.

(v) The financial or economic terms for payment, including all of the following:

(A) Eligibility criteria for a gainsharing payment.

(B) Eligibility criteria for an alignment payment.

(C) Frequency of gainsharing or alignment payment.

(D) Methodology and accounting formula for determining the amount of a gainsharing payment that is substantially based on performance across the achievement domain, efficiency domain and quality domain, and the provision of IOTA activities.

(E) Methodology and accounting formula for determining the amount of an alignment payment.

(8) The sharing arrangement must not—

(i) Induce—

(A) The IOTA participant;

(B) The IOTA collaborator; or

(C) Any employees, contractors, or subcontractors of the IOTA participant or IOTA collaborator to reduce or limit medically necessary services to any attributed patient; or

(ii) Restrict the ability of an IOTA collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies, and treatments.

(c) *Gainsharing payments and alignment payments.* (1) Gainsharing payments, if any, must meet all of the following:

(i) Be derived solely from upside risk payments.

(ii) Be distributed on an annual basis (not more than once per calendar year).

(iii) Not be a loan, advance payment, or payment for referrals or other business.

(iv) Be clearly identified as a gainsharing payment at the time it is paid.

(2) To be eligible to receive a gainsharing payment an IOTA collaborator must contribute to performance across the achievement domain, efficiency domain or quality domain for the PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment. The contribution to performance across the achievement domain, efficiency domain, or quality domain criteria must be established by the IOTA participant and directly related to the care of attributed patients.

(3) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment:

(i) An IOTA collaborator other than PGP, NPPGP, or TGP must have directly furnished a billable item or service to an attributed patient that occurred in the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment or incurred in a downside risk payment.

(ii) An IOTA collaborator that is a PGP, NPPGP, or TGP must meet the following criteria:

(A) The PGP, NPPGP, or TGP must have billed for an item or service that was rendered by one or more PGP member, NPPGP member, or TGP member respectively to an attributed patient that occurred during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment or incurred a downside risk payment.

(B) The PGP, NPPGP, or TGP must have contributed to IOTA activities and been clinically involved in the care of attributed patients during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment or incurred a downside risk payment.

(4) The total amount of a gainsharing payment for a PY paid to an IOTA collaborator that is a physician or nonphysician practitioner must not exceed 50 percent of the Medicare-approved amounts under the PFS for items and services billed by that physician or nonphysician practitioner to the IOTA participant's attributed patients during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being made.

(5) The total amount of a gainsharing payment for a PY paid to an IOTA collaborator that is a PGP, NPPGP, or TGP must not exceed 50 percent of the Medicare-approved amounts under the PFS for items and services billed by that PGP, NPPGP, or TGP and furnished to the IOTA participant's attributed patients by the PGP members, NPPGP members, or TGP members respectively during the same PY for which the IOTA participant earned the upside risk

payment that comprises the gainsharing payment being made.

(6) The amount of any gainsharing payments must be determined in accordance with a methodology that is substantially based on contribution to the performance across the achievement domain, efficiency domain or quality domain and the provision of IOTA activities. The methodology may take into account the amount of such IOTA activities provided by an IOTA collaborator relative to other IOTA collaborators.

(7) For a PY, the aggregate amount of all gainsharing payments that are derived from the upside risk payment the IOTA participant receives from CMS must not exceed the amount of that upside risk payment.

(8) No entity or individual, whether a party to a sharing arrangement or not, may condition the opportunity to make or receive gainsharing payments or to make or receive alignment payments directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent.

(9) An IOTA participant must not make a gainsharing payment to an IOTA collaborator that is subject to any action for noncompliance with this part, or the fraud and abuse laws, or for the provision of substandard care to attributed patients or other integrity problems.

(10) The sharing arrangement must require the IOTA participant to recoup any gainsharing payment that contained funds derived from a CMS overpayment on an upside risk payment or was based on the submission of false or fraudulent data.

(11) Alignment payments from an IOTA collaborator to an IOTA participant may be made at any interval that is agreed upon by both parties, and must not be—

(i) Issued, distributed, or paid prior to the calculation by CMS of a payment amount reflected in the notification of the downside risk payment;

(ii) Loans, advance payments, or payments for referrals or other business; or

(iii) Assessed by an IOTA participant if the IOTA participant does not owe a downside risk payment.

(12) The IOTA participant must not receive any amounts under a sharing arrangement from an IOTA collaborator that are not alignment payments.

(13) For a PY, the aggregate amount of all alignment payments received by the IOTA participant must not exceed 50 percent of the IOTA participant's downside risk payment amount.

(14) The aggregate amount of all alignment payments from a single IOTA collaborator to the IOTA participant may not be greater than 25 percent of the IOTA participant's downside risk payment over the course of a single PY for an IOTA collaborator.

(15) The amount of any alignment payments must be determined in accordance with a methodology that does not directly account for the volume or value of referrals or business otherwise generated by, between or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent.

(16) All gainsharing payments and any alignment payments must be administered by the IOTA participant in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book).

(17) All gainsharing payments and alignment payments must be made by check, EFT, or another traceable cash transaction.

(d) *Documentation requirements.* (1) The IOTA participant must do all of the following:

(i) Document the sharing arrangement contemporaneously with the establishment of the arrangement.

(ii) Maintain accurate current and historical lists of all IOTA collaborators, including IOTA collaborator names and addresses. With respect to these lists the IOTA participant must—

(A) Update such lists on at least a quarterly basis; and

(B) On a web page on the IOTA participant's website, the IOTA participant must—

(*1*) Publicly report the current and historical lists of IOTA collaborators; and

(*2*) Include any written policies for selecting individuals and entities to be IOTA collaborators required by the IOTA participant.

(iii) Maintain and require each IOTA collaborator to maintain contemporaneous documentation with respect to the payment or receipt of any gainsharing payment or alignment payment that includes at a minimum all of the following:

(A) Nature of the payment (gainsharing payment or alignment payment).

(B) Identity of the parties making and receiving the payment.

(C) Date of the payment.

(D) Amount of the payment.

(E) Date and amount of any recoupment of all or a portion of an IOTA collaborator's gainsharing payment.

(F) Explanation for each recoupment, such as whether the IOTA collaborator received a gainsharing payment that contained funds derived from a CMS overpayment of an upside risk payment or was based on the submission of false or fraudulent data.

(2) The IOTA participant must keep records of all of the following:

(i) Its process for determining and verifying its potential and current IOTA collaborators' eligibility to participate in Medicare.

(ii) A description of current health information technology, including systems to track upside risk payments and downside risk payments.

(iii) Its plan to track gainsharing payments and alignment payments.

(3) The IOTA participant must retain and provide access to, and must require each IOTA collaborator to retain and provide access to, the required documentation in accordance with §§ 512.460 and 1001.952(ii).

§ 512.454 Distribution arrangements.

(a) *General.* (1) An IOTA collaborator may distribute all or a portion of any gainsharing payment it receives from the IOTA participant only in accordance with a distribution arrangement, as defined at § 512.402.

(2) All distribution arrangements must comply with the provisions of this section and all other applicable laws and regulations, including the fraud and abuse laws.

(b) *Requirements.* (1) All distribution arrangements must be in writing and signed by the parties, contain the date of the agreement, and be entered into before care is furnished to attributed patients under the distribution arrangement.

(2) Participation in a distribution arrangement must be voluntary and without penalty for nonparticipation.

(3) The distribution arrangement must require the collaboration agent to comply with all applicable laws and regulations.

(4) The opportunity to make or receive a distribution payment must not be conditioned directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the IOTA participant, any IOTA collaborator, any collaboration agent, or any individual or entity affiliated with an IOTA participant, IOTA collaborator, or collaboration agent.

(5) The amount of any distribution payments from an NPPGP to an NPPGP

member, or from a TGP to a TGP member must be determined in accordance with a methodology that is substantially based on contribution to performance across the achievement domain, efficiency domain, and quality domain and the provision of IOTA activities and that may take into account the amount of such IOTA activities provided by a collaboration agent relative to other collaboration agents.

(6) The amount of any distribution payments from a PGP must be determined either in a manner that complies with § 411.352(g) of this chapter or in accordance with a methodology that is substantially based on contribution to performance across the achievement domain, efficiency domain and quality domain and the provision of IOTA activities and that may take into account the amount of such IOTA activities provided by a collaboration agent relative to other collaboration agents.

(7) Except for a distribution payment from a PGP to a PGP member that complies with § 411.352(g) of this chapter, a collaboration agent is eligible to receive a distribution payment only if the collaboration agent furnished or billed for an item or service rendered to an attributed patient that occurred during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being distributed.

(8) Except for a distribution payment from a PGP to a PGP member that complies with § 411.352(g) of this chapter, the total amount of distribution payments for a PY paid to a collaboration agent must not exceed 50 percent of the total Medicare-approved amounts under the PFS for items and services billed by that PGP, NPPGP or TGP for items and services furnished by PGP members, NPPGP members or TGP members respectively to attributed patients that occurred during the same PY for which the IOTA participant earned the upside risk payment that comprises the gainsharing payment being distributed.

(9) With respect to the distribution of any gainsharing payment received by a PGP, NPPGP, or TGP, the total amount of all distribution payments must not exceed the amount of the gainsharing payment received by the IOTA collaborator from the IOTA participant.

(10) All distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(11) The collaboration agent must retain the ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

(12) The distribution arrangement must not—

(i) Induce the collaboration agent to reduce or limit medically necessary items and services to any Medicare beneficiary; or

(ii) Reward the provision of items and services that are medically unnecessary.

(13) The IOTA collaborator must maintain contemporaneous documentation regarding distribution arrangements in accordance with § 512.454, including the following:

(i) The relevant written agreements.

(ii) The date and amount of any distribution payment(s).

(iii) The identity of each collaboration agent that received a distribution payment.

(iv) A description of the methodology and accounting formula for determining the amount of any distribution payment.

(14) The IOTA collaborator may not enter into a distribution arrangement with any collaboration agent that has a sharing arrangement with the same IOTA participant.

(15) The IOTA collaborator must retain and provide access to, and must require collaboration agents to retain and provide access to, the required documentation in accordance with § 512.460.

§ 512.455 Enforcement authority.

(a) *OIG authority.* Nothing contained in the terms of the IOTA Model or this part limits or restricts the authority of the HHS Office of Inspector General, including its authority to audit, evaluate, investigate, or inspect the IOTA participant, IOTA collaborators, or any other person or entity or their records, data, or information, without limitation.

(b) *Other authority.* Nothing contained in the terms of the IOTA Model or this part limits or restricts the authority of any government agency permitted by law to audit, evaluate, investigate, or inspect the participant hospital, CJR collaborators, or any other person or entity or their records, data, or information, without limitation.

§ 512.456 Beneficiary incentive: Part B and Part D immunosuppressive drug cost sharing support.

(a) *Cost sharing support for Part B and Part D immunosuppressive drugs.* For immunosuppressive drugs covered under Medicare Part B or Medicare Part D and prescribed to an attributed patient, the IOTA participant may subsidize, in whole or in part, the cost sharing associated with the immunosuppressive drugs under Part B and Part D immunosuppressive drug cost sharing support defined at § 512.402 if all of the following conditions are met:

(1) The attributed patient is an eligible attributed patient as defined at § 512.402.

(2) The IOTA participant must provide a written policy in a form and manner specified by CMS for the provision of Part B and Part D immunosuppressive drug cost sharing support that is approved by CMS before the PY in which the cost sharing support is made available.

(i) The IOTA participant must revalidate the written policy with CMS and in a form and manner specified by CMS for the provision of Part B and Part D immunosuppressive drug cost sharing support before its provision in a subsequent PY.

(ii) The IOTA participant's initial written policy and the revalidation of the written policy must establish and justify the criteria that qualify an eligible attributed patient to receive Part B and Part D immunosuppressive drug cost sharing support.

(iii) The IOTA participant's written policy and the revalidation of the written policy must include an attestation that the IOTA participant will not, in providing Part B and Part D immunosuppressive drug cost sharing support, take into consideration the type, cost, generic status, or manufacturer of the immunosuppressive drug(s) or limit an eligible attributed patients' choice of pharmacy.

(b) *Restrictions.* (1) An IOTA participant must not take into consideration the type, cost, generic status, or manufacturer of the immunosuppressive drug(s) or limit an eligible attributed patients' choice of pharmacy when providing Part B and Part D immunosuppressive drug cost sharing support.

(2) An IOTA participant may not receive financial or operational support for Part B and Part D immunosuppressive drug cost sharing support from pharmacies and pharmaceutical manufacturers.

(c) *Documentation.* (1) An IOTA participant must maintain contemporaneous documentation that includes:

(i) The identity of the eligible attributed patient to whom Part B and Part D immunosuppressive drug cost sharing support was provided;

(ii) The date or dates on which Part B and Part D immunosuppressive drug cost sharing support was provided; and

(iii) The amount or amounts of Part B and Part B immunosuppressive drug cost sharing support that was provided.

(2) An IOTA participant must retain and make available records pertaining to Part B and Part D immunosuppressive drug cost sharing support to the Federal Government in accordance with § 512.460.

§ 512.458 Attributed patient engagement incentives.

(a) *General.* An IOTA participant may choose to provide any or all of the following types of attributed patient engagement incentives to an attributed patient under the conditions described in paragraph (b) of this section:

(1) Communication devices and related communication services directly pertaining to communication with an IOTA participant or IOTA collaborator to improve communication between an attributed patient and an IOTA participant or IOTA collaborator.

(2) Transportation to and from an IOTA participant and between other providers and suppliers involved in the provision of ESRD care.

(3) Mental health services to address an attributed patient's behavioral health symptoms pre- and post-transplant.

(4) In-home care to support the health of the attributed patient or the kidney transplant in the post-transplant period.

(b) An IOTA participant may provide attributed patient engagement incentives of the type described in paragraph (a)(1) through (4) of this section when all of the following conditions are met:

(1) An IOTA participant provides a written policy, in a form and manner specified by CMS, for the provision of attributed patient engagement incentives.

(2) CMS approves an IOTA participants written policy before the first PY in which an attributed patient engagement incentive is first made available.

(3) CMS revalidates the IOTA participant's written policy in a form and manner specified by CMS prior to each PY in which an attributed patient engagement incentive is offered subsequently.

(4) The IOTA participant includes in its written policy:

(i) A description of the items or services that will be provided as attributed patient engagement incentives.

(ii) An explanation of how each item or service that will be an attributed patient engagement incentive has a reasonable connection to:

(A) An attributed patient achieving and maintaining active status on a kidney transplant waitlist;

(B) An attributed patient accessing the kidney transplant procedure; or

(C) The health of the attributed patient or the kidney transplant in the post-transplant period

(D) A justification for the need for the attributed patient engagement incentives that is specific to the IOTA participant's attributed patient population

(iii) An attestation that items that are attributed patient engagement incentives will be provided directly to an attributed patient.

(iv) An attestation that the IOTA participant will pay service providers directly for services that are attributed patient engagement incentives.

(v) An attestation that any items or services acquired by the IOTA participant that will be furnished as attributed patient engagement incentives will acquired for the minimum amount necessary for an attributed patient to achieve the goals described in paragraph (b)(4)(ii) of this section.

(c) *Restrictions.* (1) An IOTA participant must provide items that are attributed patient engagement incentives directly to an attributed patient.

(2) An IOTA participant must pay service providers directly for any services that are offered as attributed patient engagement incentive.

(3) An IOTA participant must not offer an attributed patient engagement incentive that is tied to the receipt of items or services from a particular provider or supplier.

(4) An IOTA participant must not advertise or promote an item or service that is an attributed patient engagement incentive, except to make an attributed patient aware of the availability of the items or services at the time an attributed patient could reasonably benefit from them.

(5) An IOTA participant may not receive donations directly or indirectly to purchase attributed patient engagement incentives.

(6) An IOTA participant must retrieve items that that are attributed patient engagement incentives from the attributed patient when the attributed patient is no longer eligible for the that item or at the conclusion of the IOTA Model, whichever is earlier.

(i) Documented, diligent, good faith attempts to retrieve items that are attributed patient engagement incentives are deemed to meet the retrieval requirement.

(ii) [Reserved]

(7) Items that are communication devices:

(i) May not exceed $1000 in retail value for any one attributed patient in any one PY.

(ii) Must remain the property of the IOTA participant;

(iii) Must be retrieved from the attributed patient by the IOTA participant—

(A) When the attributed patient is no longer eligible for the communication device or at the conclusion of the IOTA Model, whichever is earlier; and

(B) Before another communication device may be made available to the same attributed patient.

(d) *Documentation.* (1) The IOTA participant must maintain contemporaneous documentation of items and services furnished as attributed patient engagement incentives that includes, at minimum all of the following:

(i) The date the attributed patient engagement incentive is provided.

(ii) The identity of the attributed patient to whom the item or service was provided.

(2) Retrieval documentation.

(i) IOTA participants must document all retrieval attempts of items that are attributed patient engagement incentives, including the ultimate date of retrieval.

(ii) [Reserved]

(3) The IOTA participant must retain records pertaining to furnished attributed patient engagement incentives and make these records available to the Federal Government in accordance with § 512.460.

§ 512.459 Application of the CMS-sponsored model arrangements and patient incentives safe harbor.

(a) *Application of the CMS-sponsored Model Arrangements Safe Harbor.* CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (§ 1001.952(ii)(1) of this chapter) is available to protect remuneration furnished in the IOTA Model in the form of Sharing Arrangement's gainsharing payments, Sharing Arrangement's alignment payments, and the Distribution Arrangement's distribution payments that meet all safe harbor requirements set forth in § 1001.952(ii) this chapter, and §§ 512.452 and 512.454.

(b) *Application of the CMS-sponsored Model Patient Incentives Safe Harbor.* CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (§ 1001.952(ii)(2) of this chapter) is available to protect remuneration furnished in the IOTA model in the form of Part B and Part D immunosuppressive drug cost sharing support and the attributed patient engagement incentives that meet all safe

harbor requirements set forth in § 1001.952(ii) of this chapter, and §§ 512.456 and 512.458.

§ 512.460 Audit rights and records retention.

(a) *Right to audit.* The Federal Government, including CMS, HHS, and the Comptroller General, or their designees, has the right to audit, inspect, investigate, and evaluate any documents and other evidence regarding implementation of the IOTA Model.

(b) *Access to records.* The IOTA participant and its IOTA collaborators must maintain and give the Federal Government, including, but not limited to, CMS, HHS, and the Comptroller General, or their designees, access to all such documents (including books, contracts, and records) and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the implementation of the IOTA Model, including without limitation, documents, and other evidence regarding all of the following:

(1) Compliance by the IOTA participant and its IOTA collaborators with the terms of the IOTA Model.

(2) The accuracy of model-specific payments made under the IOTA Model.

(3) The IOTA participant's downside risk payments owed to CMS under the IOTA Model.

(4) Quality measure information and the quality of services performed under the terms of the IOTA Model.

(5) Utilization of items and services furnished under the IOTA Model.

(6) The ability of the IOTA participant to bear the risk of potential losses and to repay any losses to CMS, as applicable.

(7) Contemporaneous documentation of cost sharing support furnished under Part B and Part D immunosuppressive drug cost sharing support that includes the following:

(i) The identity of the eligible attributed patient to whom Part B and Part D immunosuppressive drug cost sharing support was provided.

(ii) The date or dates on which Part B and Part D immunosuppressive drug cost sharing support was provided.

(iii) The amount or amounts of the cost sharing support provided to the attributed patient.

(8) Contemporaneous documentation of items and services furnished as attributed patient engagement incentives in accordance with § 512.458 that includes all of the following, at minimum:

(i) The date the attributed patient engagement incentive is provided.

(ii) The identity of the attributed patient to whom the item or service was provided.

(9) Patient safety.

(10) Any other program integrity issues.

(c) *Record retention.* (1) The IOTA participant and its IOTA collaborators must maintain the documents and other evidence described in paragraph (b) of this section and other evidence for a period of 6 years from the last payment determination for the IOTA participant under the IOTA Model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the IOTA participant at least 30 days before the normal disposition date; or

(ii) There has been a termination, dispute, or allegation of fraud or similar fault against the IOTA participant or its IOTA collaborators, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

(2)(i) If CMS notifies the IOTA participant of the special need to retain a record or group of records in accordance with paragraph (c)(1)(i) of this section, the IOTA participant must maintain the records for such period of time as determined by CMS.

(ii) If CMS notifies the IOTA participant of a special need to retain records in accordance with this paragraph (c)(1)(ii), the IOTA participant must notify its IOTA collaborators of this need to retain records for the additional period specified by CMS.

§ 512.462 Compliance and monitoring.

(a) *Compliance with laws.* The IOTA participant must comply with all applicable laws and regulations.

(b) *CMS monitoring activities.* (1) CMS, or its approved designee, may conduct monitoring activities to ensure compliance by the IOTA participant and IOTA collaborators with the terms of the IOTA Model under this subpart to—

(i) Understand IOTA participants' use of model-specific payments; and

(ii) Promote the safety of attributed patients and the integrity of the IOTA Model.

(2) Monitoring activities may include, without limitation, all of the following:

(i) Documentation requests sent to the IOTA participant and its IOTA collaborators, including surveys and questionnaires.

(ii) Audits of claims data, quality measures, medical records, and other data from the IOTA participant and its IOTA collaborators.

(iii) Interviews with the IOTA participant, including leadership personnel, medical staff, other associates, and its IOTA collaborators.

(iv) Interviews with attributed patients and their caregivers.

(v) Site visits to the IOTA participant and its IOTA collaborators, performed in a manner consistent with paragraph (c) of this section.

(vi) Monitoring quality outcomes and attributed patient data.

(vii) Tracking beneficiary complaints and appeals.

(viii) Monitor the definition of and justification for the subpopulation of the IOTA participant's eligible attributed patients that may receive Part B and Part D Immunosuppressive Drug Cost Sharing Support in accordance with § 512.456.

(ix) Monitor the provision of attributed patient engagement incentives provided in accordance with § 512.458.

(x) Monitor out of sequence allocation of kidneys by—

(A) Assessing the frequency at which IOTA waitlists patients, top-ranked on an IOTA participant's kidney transplant waitlist, receive the organ that was initially offered to them; and

(B) Determining the reasons behind cases where IOTA waitlist patients identified in paragraph (b)(x)(A) of this section, did not receive the kidney offered to them.

(3) In conducting monitoring and oversight activities, CMS or its designees may use any relevant data or information including without limitation all Medicare claims submitted for items or services furnished to IOTA transplant patients or IOTA waitlist patients or both.

(c) *Site visits.* (1) The IOTA participant must cooperate in periodic site visits performed by CMS or its designees in order to facilitate the evaluation of the IOTA Model in accordance with section 1115A(b)(4) of the ACT and the monitoring of the IOTA participant's compliance with the terms of the IOTA Model, including this subpart.

(2) When scheduling the site visit, CMS or its designee provides, to the extent practicable, the IOTA participant with no less than 15 days advance notice of any site visit. CMS—

(i) Attempts, to the extent practicable, to accommodate a request for particular dates in scheduling site visits; and

(ii) Does not accept a date request from the IOTA participant that is more

than 60 days after the date of the initial site visit notice from CMS.

(3) The IOTA participant must ensure that personnel with the appropriate responsibilities and knowledge associated with the purpose of the site visit are available during all site visits.

(4) CMS may perform unannounced site visits at the office of the IOTA participant at any time to investigate concerns about the health or safety of attributed patients or other program integrity issues.

(5) Nothing in this part may be construed to limit or otherwise prevent CMS from performing site visits permitted or required by applicable law.

(d) *Reopening of payment determinations.* (1) CMS may reopen an IOTA Model-specific payment determination on its own motion or at the request of the IOTA participant, within 4 years from the date of the determination, for good cause (as defined at § 512.462) except if there exists reliable evidence that the determination was procured by fraud or similar fault as defined in § 512.464. In the case of fraud or similar fault, CMS may reopen an IOTA Model specific payment determination at any time.

(2) CMS' decision regarding whether to reopen a model-specific payment determination is binding and not subject to appeal.

§ 512.464 Remedial action.

(a) *Grounds for remedial action.* CMS may impose one or more remedial actions described in paragraph (b) of this section if CMS determines that:

(1) The IOTA participant has failed to furnish 11 or more transplants during a PY or any baseline years.

(2) The IOTA participant or its IOTA collaborator has failed to comply with any of the terms of the IOTA Model, including this subpart.

(3) The IOTA participant has failed to comply with transparency requirements described at § 512.442.

(4) The IOTA participant or its IOTA collaborator has failed to comply with any applicable Medicare program requirement, rule, or regulation.

(5) The IOTA participant or its IOTA collaborator has taken any action that threatens the health or safety of an attributed patient.

(6) The IOTA participant or its IOTA collaborator has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the IOTA Model.

(7) The IOTA participant or its IOTA collaborator has undergone a Change in Control that presents a program integrity risk.

(8) The IOTA participant or its IOTA collaborator is subject to any sanctions of an accrediting organization or a Federal, State, or local government agency.

(9) The IOTA participant or its IOTA collaborator is subject to investigation or action by HHS (including the HHS Office of Inspector General or CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including any of the following:

(i) Being subject to the filing of a complaint or filing of a criminal charge.

(ii) Being subject to an indictment.

(iii) Being named as a defendant in a False Claims Act qui tam matter in which the Federal Government has intervened, or similar action.

(10) The IOTA participant or its IOTA collaborator has failed to demonstrate improved performance following any remedial action imposed under this section.

(11) The IOTA participant has misused or disclosed beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the applicable data sharing agreement.

(b) *Remedial actions.* If CMS determines that one or more grounds for remedial action described in paragraph (a) of this section has taken place, CMS may take one or more of the following remedial actions:

(1) Notify the IOTA participant and, if appropriate, require the IOTA participant to notify its IOTA collaborators of the violation.

(2) Require the IOTA participant to provide additional information to CMS or its designees.

(3) Subject the IOTA participant to additional monitoring, auditing, or both.

(4) Prohibit the IOTA participant from distributing model-specific payments, as applicable.

(5) Require the IOTA participant to terminate, immediately or by a deadline specified by CMS, its sharing arrangement with an IOTA collaborator with respect to the IOTA Model.

(6) Terminate the IOTA participant from the IOTA Model.

(7) Suspend or terminate the ability of the IOTA participant to provide Part B and Part D immunosuppressive drug cost sharing support in accordance with § 512.456 or attributed patient engagement incentives in accordance with § 512.458.

(8) Require the IOTA participant to submit a corrective action plan in a form and manner and by a deadline specified by CMS.

(9) Discontinue the provision of data sharing and reports to the IOTA participant.

(10) Recoup model-specific payments.

(11) Reduce or eliminate a model-specific payment otherwise owed to the IOTA participant.

(13) Any other action as may be permitted under the terms of this part.

§ 512.466 Termination.

(a) *Termination of IOTA participant from the IOTA Model by CMS.* CMS may immediately or with advance notice terminate an IOTA participant from participation in the model if CMS does any of the following:

(1) Determines that it no longer has the funds to support the IOTA Model.

(2) Modifies or terminates the IOTA Model in accordance with section 1115A(b)(3)(B) of the Act.

(3) Determines that the IOTA participant—

(i) Has failed to comply with any model requirements or any other Medicare program requirement, rule, or regulation;

(ii) Has failed to comply with a monitoring or auditing plan or both;

(iii) Has failed to submit, obtain approval for, implement or fully comply with the terms of a CAP;

(iv) Has failed to demonstrate improved performance following any remedial action;

(v) Has taken any action that threatens the health or safety of a Medicare beneficiary or other patient;

(vi) Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the IOTA Model;

(vii) Assigns or purports to assign any of the rights or obligations under the IOTA Model, voluntarily or involuntarily, whether by merger, consolidation, dissolution, operation of law, or any other manner, without the written consent of CMS;

(viii) Poses significant program integrity risks, including but not limited to—

(A) Is subject to sanctions or other actions of an accrediting organization or a Federal, State, or local government agency; or

(B) Is subject to investigation or action by HHS (including OIG and CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint, filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the government has intervened, or similar action.

(b) *Termination of Model participation by IOTA participant.* The IOTA participant may not terminate their participation in the IOTA Model.

(c) *Financial settlement upon termination.* If CMS terminates the IOTA participant's participation in the IOTA Model, CMS calculates the final performance score and any upside risk payment or downside risk payment, if applicable, for the entire PY in which the IOTA participant's participation in the model was terminated.

(1) If CMS terminates the IOTA participant's participation in the IOTA Model, CMS determines the IOTA participant's effective date of termination.

(2) If CMS terminates the IOTA participant for any reasons listed under § 512.466:

(i) CMS does not make any payments of upside risk payment for the PY in which the IOTA participant was terminated; and

(ii) The IOTA participant will remain liable for payment of any downside risk payment up to and including the PY in which termination becomes effective.

(d) *Termination of the IOTA Model by CMS.* (1) The general provisions for the Innovation Center model termination by CMS listed under § 512.165 will apply to the IOTA Model.

(i) CMS may terminate the IOTA Model for reasons including, but not limited to, those set forth in § 512.165(a).

(ii) If CMS terminates the IOTA Model, CMS provides written notice to IOTA participants specifying the grounds for model termination and the effective date of such termination.

(2) In accordance with section 1115A(d)(2) of the Act and § 512.170(e), termination of the IOTA Model under section 1115A(b)(3)(B) of the Act is subject to administrative or judicial review.

(3) If CMS terminates the IOTA Model, the financial settlement terms described in paragraph (c) of this section applies.

§ 512.468 Bankruptcy and other notifications.

(a) *Notice of bankruptcy.* (1) If the IOTA participant has filed a bankruptcy petition, whether voluntary or involuntary, the IOTA participant must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment has been made by either CMS or the IOTA participant under the terms of each model tested under section 1115A of the Act in which the IOTA participant is participating or has participated and all administrative or judicial review proceedings relating to any payments under such models have been fully and finally resolved.

(2) The notice of bankruptcy must meet all of the following:

(i) Be sent by certified mail no later than 5 days after the petition has been filed.

(ii) Contain—

(A) A copy of the filed bankruptcy petition (including its docket number); and

(B) A list of all models tested under section 1115A of the Act in which the IOTA participant is participating or has participated.

(b) *Change in control.* (1) The IOTA participant must provide written notice to CMS at least 90 days before the effective date of any change in control.

(2) CMS may terminate an IOTA participant from the IOTA Model if the IOTA participant undergoes a change in control.

(c) *Prohibition on assignment.* (1) Unless CMS provides prior written consent, an IOTA participant must not transfer, including by merger (whether the IOTA participant is the surviving or disappearing entity), consolidation, dissolution, or otherwise any—

(i) Discretion granted it under the model;

(ii) Right that it has to satisfy a condition under the model;

(iii) Remedy that it has under the model; or

(iv) Obligation imposed on it under the model.

(2) The IOTA participant must provide CMS 90 days advance written notice of any such proposed transfer.

(3) This obligation remains in effect after the expiration or termination of the model, or the IOTA participant's participation in the model, and until final payment by the IOTA participant under the model has been made.

(4) CMS may condition its consent to such transfer on full or partial reconciliation of upside risk payments and downside risk payments.

(5) Any purported transfer in violation of this requirement is voidable at the discretion of CMS.

Waivers

§ 512.470 Waivers.

CMS waives the requirements of sections 1881(b), 1833(a) and (b) of the Act only to the extent necessary to make the payments under the IOTA Model described in this subpart.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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Part III

Department of Labor

Employee Benefits Security Administration

29 CFR Parts 2520, 2550, and 2578

Abandoned Plan Regulations and Prohibited Transaction Exemption 2006–06 for Services Provided in Connection With the Termination of Abandoned Individual Account Plans; Interim Final Rules

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Parts 2520, 2550, and 2578

RIN 1210–AC04

Abandoned Plan Regulations

AGENCY: Employee Benefits Security Administration, Department of Labor.

ACTION: Interim final rules with request for comments.

SUMMARY: This rulemaking amends the Abandoned Plan Program regulations that provide streamlined procedures for the termination of, and distribution of benefits from, individual account pension plans that have been abandoned by their sponsoring employers. The regulations, which were adopted in 2006 under the Employee Retirement Income Security Act of 1974, as amended (''ERISA''), did not cover individual account pension plans whose sponsors are in liquidation under chapter 7 of the U.S. Bankruptcy Code. These interim final rules expand the regulations to cover these plans so that bankruptcy trustees may use the Abandoned Plan Program's streamlined procedures to terminate and wind them up. Other technical amendments also are being made to improve the efficiency and operation of the Abandoned Plan Program. The amendments will affect employee benefit plans (primarily small defined contribution plans), participants and beneficiaries, service providers, and individuals appointed to serve as bankruptcy trustees under chapter 7 of the U.S. Bankruptcy Code. The Department is also issuing an amendment to PTE 2006–06, the prohibited transaction exemption accompanying the Abandoned Plan Program regulations, elsewhere in this issue of the **Federal Register**.

DATES:

Effective Date. These interim final rules are effective on July 16, 2024.

Comment Due Date. Comments on these interim final rules are due on July 16, 2024.

ADDRESSES: Interested persons are encouraged to submit their comments on these interim final rules online. You may submit comments, identified by RIN 1210–AC04, by either of the following methods:

Federal eRulemaking Portal: www.regulations.gov. Follow the instructions for submitting comments.

Mail: Office of Regulations and Interpretations, Employee Benefits Security Administration, Room N–5655, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210, Attn: Amendments to the Abandoned Plan Program regulations interim final rules RIN 1210–AC04.

Instructions: All submissions must include the agency name and Regulatory Identifier Number (RIN 1210–AC04) for this rulemaking. If you submit comments online, do not submit paper copies. *Warning:* Do not include any personally identifiable or confidential business information that you do not want publicly disclosed. Comments are public records that are posted online as received and can be retrieved by most internet search engines.

Docket: Comments will be available to the public, without charge, online at the Federal eRulemaking Portal at *http://www.regulations.gov,* on the Department's website at *http://www.dol.gov/agencies/ebsa,* and at the Public Disclosure Room, Employee Benefits Security Administration, Room N–1513, 200 Constitution Ave., NW, Washington, DC 20210. The plain-language summary of the interim final rules of not more than 100 words in length required by the Providing Accountability Through Transparency Act of 2023, and any other background documents, also can be accessed at the Federal eRulemaking Portal at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Thomas M. Hindmarch or Jason Dewitt, Office of Regulations and Interpretations, Employee Benefits Security Administration, (202) 693–8500. This is not a toll-free number.

SUPPLEMENTARY INFORMATION:

A. Summary Overview

On April 21, 2006, the Department of Labor issued three regulations that established the Employee Benefits Security Administration's (EBSA) Abandoned Plan Program to facilitate the orderly and efficient termination of, and distribution of benefits from, individual account pension plans that have been abandoned by their sponsoring employers.[1]

The first regulation establishes standards for determining when individual account plans may be considered ''abandoned'' and procedures by which financial institutions, called ''qualified termination administrators'' (QTAs), holding the assets of such plans may terminate the plans and distribute benefits to participants and beneficiaries, with limited liability under Title I of the Employee Retirement Income Security Act (ERISA).[2] The second regulation provides a fiduciary safe harbor for QTAs to make distributions on behalf of participants and beneficiaries who fail to elect a form of benefit distribution. These participants and beneficiaries are sometimes referred to as ''missing participants.'' [3] The third regulation establishes a simplified method for filing a terminal report for abandoned individual account plans.[4]

The 2006 regulations were accompanied by a prohibited transaction exemption, PTE 2006–06, which facilitates the goal of the Abandoned Plan Program by permitting a QTA who meets the conditions in the exemption to select itself or an affiliate to carry out the termination and winding-up activities specified in the 2006 regulations. The exemption also allows a QTA to pay itself or an affiliate for those services.[5]

For the reasons set forth in the 2006 preamble, the Abandoned Plan Program regulations strictly limit who may be a QTA.[6] To be a QTA, an entity must:

(1) be eligible to serve as a trustee or issuer of an individual retirement plan within the meaning of section 7701(a)(37) of the Internal Revenue Code and

(2) hold assets of the plan on whose behalf it will serve as the QTA.[7]

As a result of these conditions, bankruptcy trustees ordinarily do not qualify as QTAs under the Abandoned Plan Program regulations. This means the regulations and the class exemption generally are not available with respect to plans whose sponsors are in liquidation under chapter 7 of the Bankruptcy Code. This was expressly acknowledged and discussed in the preamble when the Department published the Abandoned Plan Program regulations in 2006.[8]

For several reasons, the Department decided to revisit its decision to preclude bankruptcy trustees from serving as QTAs. The Department believed and continues to believe that when an individual account plan

[1] 71 FR 20820. *See also,* 73 FR 58459 (Oct. 7, 2008) for subsequent amendments with regard to distributions on behalf of a missing non-spouse beneficiary.

[2] 29 CFR 2578.1.

[3] 29 CFR 2550.404a–3. This safe harbor also is available to fiduciaries of terminated individual account plans that are not abandoned.

[4] 29 CFR 2520.103–13.

[5] *See* PTE 2006–06, 71 FR 20855 (Apr. 21, 2006) as amended at 73 FR 58629 (Oct. 7, 2008) (distributions on behalf of a missing non-spouse beneficiary).

[6] 71 FR at 20821.

[7] 29 CFR 2578.1(g).

[8] 71 FR at 20821.

sponsor is in liquidation in a chapter 7 bankruptcy case, the plan should be terminated and wound up in an orderly and efficient manner. In bankruptcy cases, as with abandoned plans generally, the sponsor usually is not able to carry out this function. Instead, the Department expected that, in chapter 7 bankruptcy cases, the appointed bankruptcy trustee would take the necessary steps to terminate the plan, wind up its affairs, and distribute plan benefits.

The issue of the bankruptcy trustee's authority to terminate and wind up the plan was addressed by the enactment of 11 U.S.C. 704(a)(11) as part of the Bankruptcy Abuse Prevention and Consumer Protection Act of 2005 (BAPCPA).[9] Under that provision, when an entity that sponsors an individual account plan is liquidated under chapter 7 of the Bankruptcy Code, the appointed bankruptcy trustee administering the liquidation proceeding is required to continue to perform the plan administration obligations that would otherwise be required of the bankrupt entity.[10]

Based on its experience administering the Abandoned Plan Program, the Department concluded that the termination of individual account plans of sponsors in liquidation under chapter 7 (Chapter 7 ERISA Plans) could be improved by including bankruptcy trustees as QTAs and providing streamlined termination and winding up procedures that are applicable to them [11] Thus, on December 12, 2012, the Department published proposed amendments to the 2006 regulations.[12] The purpose of the regulatory action was to advance the interests of participants and beneficiaries by:

(1) facilitating the orderly and efficient termination of Chapter 7 ERISA Plans,

(2) reducing administrative burden and costs imposed on Chapter 7 ERISA Plans that terminate in accordance with the regulations, and

(3) providing an avenue for bankruptcy trustees to discharge their duties under ERISA and the Bankruptcy Code with respect to Chapter 7 ERISA Plans.

Other technical amendments were also proposed to improve the operation of the program.

The Department received seven written comment letters on the 2012 proposal, on behalf of bankruptcy trustees, service providers and financial institutions, the Federal Deposit Insurance Corporation (FDIC) in its receivership role, and plan participant representatives. The commenters generally supported the program's expansion to include Chapter 7 ERISA Plans and identified several areas in which they thought the proposal could be improved. The written comments on the 2012 proposal are available on the Department's website.[13]

The Department has concluded that expanding the Abandoned Plan Program regulations to cover Chapter 7 ERISA Plans and making other technical changes in response to the public comments would result in an improved Abandoned Plan Program. The Department acknowledges that it has been over 10 years since the comment period closed. However, the purposes of the regulatory action and the rationale for the changes discussed in the 2012 proposal continue to be relevant, and the program's expansion to include Chapter 7 ERISA Plans and adoption of certain other technical improvements would advance the interests of participants and beneficiaries in abandoned plans.

The Department is relying on its earlier proposal, its consideration of comments on that proposal, and its understanding of the challenges facing these plans to finalize these interim final rules. The Department acknowledges the delay in finalizing the rules and therefore also believes another round of public comments would help it evaluate the further program expansions suggested by some stakeholders and other possible program improvements to address potential changes in marketplace circumstances and stakeholder experiences with abandoned plans. Accordingly, the Department is adopting these amendments to the Abandoned Plan Program regulations in the form of interim final rules with a request for comments.

B. Abandoned Plan Program Special Rules for Chapter 7 ERISA Plans—§ 2578.1

The new provisions for Chapter 7 ERISA Plans are contained in paragraph (j) of 29 CFR 2578.1. The amendments extend the Abandoned Plan Program's termination and winding up procedures to Chapter 7 ERISA Plans. New paragraph (j) is largely an overlay on the existing program. This overlay approach enabled the Department to adapt the 2006 regulations to Chapter 7 ERISA Plans without overhauling the framework of the Abandoned Plan Program.

In terminating a Chapter 7 ERISA Plan, a QTA would generally apply the ''winding up procedures'' in paragraph (d) of § 2578.1 except to the extent that such procedures are modified by paragraph (j). Paragraph (j) provides that such plans are deemed abandoned upon the bankruptcy court's entry of an order for relief in the plan sponsor's liquidation proceeding. Paragraph (j) then allows the bankruptcy trustee or an ''eligible designee'' to be the QTA, terminate and wind up the plan using the streamlined procedures, and pay itself reasonable compensation from plan assets for these services. A corresponding edit to paragraph (e) of § 2578.1 makes clear that the limited relief from ERISA's fiduciary liability provisions applies to a bankruptcy trustee that complies with paragraph (j)(7). When EBSA has determined that the QTA (whether bankruptcy trustee or eligible designee) has completed its responsibilities under the program, EBSA will provide a letter to the QTA entitled Receipt of Final Notice.

Paragraph (j) allows and in some cases mandates the bankruptcy trustee to appoint an ''eligible designee'' to terminate and wind up the plan under the streamlined procedures of the Abandoned Plan Program. Paragraph (j) recognizes only two types of eligible designees:

- an entity that can serve as a QTA under paragraph (g) of § 2578.1 (*i.e.,* an entity that is eligible to serve as a trustee or issuer of an individual retirement plan within the meaning of section 7701(a)(37) of the Internal Revenue Code and that holds assets of the plan on whose behalf it will serve as the QTA).
- a person who has served within the previous five years as a bankruptcy trustee in a case under chapter 7 of the Bankruptcy Code (referred to herein as the ''independent bankruptcy trustee practitioner'').

If appointed, the eligible designee would serve as the plan's QTA and

[9] Public Law 109–8, 119 Stat. 23.

[10] Section 704(a)(11) refers to whether the debtor (or any entity designated by the debtor) serves as the administrator (as defined in ERISA section 3) of an employee benefit plan. ERISA section 3(16) defines the ''administrator'' as the plan sponsor in the absence of any designation in the plan document of another person as administrator.

[11] The proposal referred to these plans as ''chapter 7 plans.'' The new term ''Chapter 7 ERISA Plans'' is used in these interim final rules for avoidance of confusion regarding the term ''plan'' used in the bankruptcy context.

[12] 77 FR 74063. The Department also published in the same issue of the **Federal Register** proposed amendments to class exemption PTE 2006–06 addressing the various transactions related to the proposed amendments to the regulations. 77 FR 74055.

[13] Available at *www.dol.gov/agencies/ebsa/laws-and-regulations/rules-and-regulations/public-comments/1210-AB47.*

would terminate and wind up the plan in accordance with these interim final rules. In this regard, the eligible designee's responsibilities in winding up the affairs of the plan would be the same as those of the bankruptcy trustee if it had elected to act as the QTA. While the United States Trustee Program maintains oversight authority of the bankruptcy trustee under 28 U.S.C. 586, including the performance of trustee duties under 11 U.S.C. 704,[14] the Department emphasizes that the use of the Abandoned Plan Program and winding up procedures under paragraphs (d) and (j) of section 2578.1 are governed by ERISA (and subject to Department oversight).

The eligible designee is acting under the authority of ERISA and 29 CFR 2578.1(j) and the designation under the IFR does not confer upon any party to the bankruptcy proceeding the ability to make a claim upon any bond held by the eligible designee under the Federal Rules of Bankruptcy Procedure.[15] The Department views the bankruptcy trustees' and eligible designees' activities under the Abandoned Plan Program as subject to ERISA and Department oversight. This would include, for example, a bankruptcy trustee's designation of an independent bankruptcy trustee practitioner as an eligible designee, a bankruptcy trustee's or eligible designee's hiring of plan service providers, and a bankruptcy trustee's or eligible designee's decision to pay itself or another service provider from plan assets.[16]

While the procedures and requirements in these interim final rules are voluntary, in the Department's view, a bankruptcy trustee that follows the interim final rules should generally be able to reduce its administrative burden and costs.[17] A more detailed description of the cost savings attributable to relieving the bankruptcy trustee from the obligation to file annual reports can be found in the Regulatory Impact Analysis section of this preamble.

1. Bankruptcy Trustee as Qualified Termination Administrator—§ 2578.1(j)(3)

These interim final rules generally adopt the provision from the 2012 proposal that allows the bankruptcy trustee in the case to elect to serve as the QTA. For purposes of the interim final rules, the bankruptcy trustee in the case includes the interim trustee appointed after the order for relief is entered, as well as an elected trustee if applicable.[18] The bankruptcy trustee would have to satisfy the winding up procedures in paragraphs (d) and (j) of § 2578.1 as discussed herein. A bankruptcy trustee that satisfies the conditions of the interim final rules is entitled to reasonable compensation for its services and also is entitled to the fiduciary liability relief provided by paragraph (e) of § 2578.1.

As stated above, commenters were generally supportive of the program's expansion to include Chapter 7 ERISA Plans. One commenter expressed the view that the goals of the Abandoned Plan Program could be furthered by reducing the role of the bankruptcy trustee as much as possible in favor of having another QTA (*i.e.,* the plan's asset custodian eligible to serve under paragraph (g)) wind up these plans. The commenter stated that a chapter 7 bankruptcy trustee must always remain ''disinterested'', which meant that the trustee could not represent the interests of both the bankruptcy estate and an adverse party to the estate at the same time. The commenter cited several specific concerns with a bankruptcy trustee having ongoing responsibilities to an ERISA plan until its termination. The concerns included the trustee's lack of expertise in monitoring ERISA plan termination; perceived conflicts between a trustee's role with respect to the bankruptcy estate and as QTA for the terminating ERISA plan; and interaction between the requirements of the proposal and the established practices of seeking bankruptcy court approval for any ''out-of-the-ordinary-course-activity'' in administering the bankruptcy estate. The commenter also expressed concern that an ongoing role for the bankruptcy trustee could conflict with its obligation to close the estate expeditiously. For these reasons, the commenter believed that a chapter 7 bankruptcy trustee's responsibilities should be discharged by the appointment of an asset custodian eligible designee as QTA and the provision of information in the trustee's possession to the QTA.

The Department has carefully considered this comment and has made some changes in these interim final rules, as discussed below, including requiring that the bankruptcy trustee appoint an eligible designee to be the QTA in certain circumstances. In considering the potential breadth of the changes, the Department was mindful of the fact that, in BAPCPA, Congress assigned the obligations of an ERISA plan administrator to chapter 7 bankruptcy trustees. Therefore, it does not appear that Congress saw a fundamental conflict between a trustee's role with respect to the bankruptcy estate and its role in terminating the ERISA plan. As a result of this statutory assignment of responsibility, the Department does not believe it is appropriate to adopt a framework in which the chapter 7 bankruptcy trustee would have no ongoing obligation to the plan after appointment of an eligible designee.[19]

2. Appointing an Eligible Designee as QTA—§ 2578.1 (j)(4) and (j)(5)

The 2012 proposal featured a provision that allowed bankruptcy trustees to appoint eligible designees to wind up Chapter 7 ERISA Plans, rather than the bankruptcy trustee serving as the QTA. Although, as discussed in the following preamble sections, public comments disagreed on the proper scope and effect of such an appointment, commenters focusing on the appointment provision generally

[14] Bankruptcy administrators oversee the administration of bankruptcy cases filed in Alabama and North Carolina.

[15] *See* 11 U.S.C. 322; Federal Rule of Bankruptcy Procedure 2010.

[16] *See Kirschenbaum* v. *U.S. Dept. of Labor (In re Robert Plan Corp.),* 777 F.3d 594 (2d Cir. 2015) (bankruptcy courts do not have jurisdiction to award compensation to a chapter 7 bankruptcy trustee and retained professionals out of assets in a 401(k) plan governed by ERISA).

[17] A bankruptcy trustee that decides not to use the streamlined procedures of the program will not have the fiduciary relief provided under the program with respect to the termination and winding up of the plan and will have to complete and file all annual reports (past due or otherwise) and furnish the attendant summary annual reports to participants as would be required of any other plan administrator. The Department expects that the costs savings to the plan and its participants and beneficiaries will also be an important factor for bankruptcy trustees in deciding to use the program.

[18] *See* 11 U.S.C. 702(b) and (d).

[19] One commenter argued that § 704(a)(11) does not make the chapter 7 bankruptcy trustee the plan administrator but rather requires it to ''perform the obligation required of the administrator[.]'' In this circumstance, the Department does not believe there is a meaningful distinction between the two. The Bankruptcy Abuse Prevention and Consumer Protection Act of 2005, Report of the Committee on the Judiciary House of Representatives, to accompany S. 256, states at p. 19: ''[T]he bill streamlines the appointment of an ERISA administrator for an employee benefit plan, under certain circumstances, to minimize the disruption that results when an employer files for bankruptcy relief.'' The report states at page 96: ''Subsection (a) of section 446 of the Act amends Bankruptcy Code section 521(a) to require a debtor, unless a trustee is serving in the case, to serve as the administrator (as defined in the Employee Retirement Income Security Act of 1974) of an employee benefit plan if the debtor served in such capacity at the time the case was filed. Section 446(b) amends Bankruptcy Code section 704 to require the chapter 7 trustee to perform the obligations of such administrator in a case where the debtor or an entity designated by the debtor was required to perform such obligations. Section 446(c) amends Bankruptcy Code section 1106(a) to require a chapter 11 trustee to perform these obligations.'' Report is available at *www.congress.gov/congressional-report/109th-congress/house-report/31/1.*

supported the idea. Accordingly, these interim final rules adopt the appointment feature with certain modifications.

(a) Who may be an eligible designee?

These interim final rules change the 2012 proposal's limits on who may be an eligible designee. An eligible designee is an important position under the interim final rules because, after accepting its appointment, the eligible designee serves as the QTA and is responsible for terminating and winding up the plan in accordance with the interim final regulations.

Under the proposal, an ''eligible designee'' was strictly limited to any person or entity designated by the bankruptcy trustee that is eligible to serve as a trustee or issuer of an individual retirement plan, within the meaning of section 7701(a)(37) of the Internal Revenue Code, and that holds assets of the Chapter 7 ERISA Plan. Thus, an eligible designee could be the plan's asset custodian at the time of abandonment, or another entity chosen by the bankruptcy trustee.

Under these interim final rules, the bankruptcy trustee may appoint either a plan asset custodian described above or an independent bankruptcy trustee practitioner to be the eligible designee. An independent bankruptcy trustee practitioner is not the trustee for that particular chapter 7 case, but has served within the previous five years as a bankruptcy trustee in a case under chapter 7 of the Bankruptcy Code. The person could have served as a bankruptcy trustee in a case under chapter 7 pursuant to an appointment by the United States Trustee (or a bankruptcy administrator, if applicable) to a panel for chapter 7 liquidations, pursuant to an election, or by another reason such as being the bankruptcy trustee in a chapter 11 case that converts to a chapter 7 case. In addition, to be an eligible designee, the independent bankruptcy trustee practitioner must acknowledge its ERISA fiduciary status in writing.[20]

The decision to appoint an eligible designee to be the QTA is voluntary on the part of the bankruptcy trustee unless it determines that the Chapter 7 ERISA Plan is owed delinquent contributions (employer and employee) of more than a de minimis amount, as defined in the interim final rules. In that case, the interim final rules require the bankruptcy trustee to appoint an eligible designee. This change responds to comments expressing concern about potential conflicts of interest if the same bankruptcy trustee is assigned to represent the interests of the estate and to terminate the ERISA plan, and more specifically, the requirement to take reasonable steps to collect delinquent contributions on behalf of the plan unless such amounts are de minimis. The interim final rule mandates appointment of an eligible designee in these circumstances so as to address commenters' perceived potential for a conflict of interest on the part of the bankruptcy trustee. The Department stresses, however, that the bankruptcy trustee retains fiduciary responsibility under section 404(a) of ERISA for prudently and loyally selecting and monitoring the eligible designee.

These interim final rules also define ''eligible designee'' to address comments asking for clarification that an entity or person is not an eligible designee unless it acknowledges and accepts that designation. Some commenters were concerned that a bankruptcy trustee could force an entity to be an eligible designee and suggested that a bankruptcy trustee's appointment of and acceptance by the eligible designee should be formalized in writing. In response to these comments, the interim final rules clarify in paragraphs (j)(4)(i) and (ii) of § 2578.1 that, in addition to the other specified conditions, an eligible designee must accept such designation in writing. The Department does not believe it is necessary to prescribe rules for exactly how a bankruptcy trustee and an eligible designee should effect the designation and acceptance. However, the Department seeks comment on whether a model acceptance would be useful.

(b) What conditions are necessary to appoint an eligible designee?

The conditions to appoint an eligible designee are set forth in paragraphs (j)(5)(ii) through (v) of § 2578.1.

First, prior to designating an eligible designee, a bankruptcy trustee must make reasonable and diligent efforts to determine whether the plan is owed any contributions (employer and employee). Whether the plan is owed more than a ''de minimis'' amount of contributions will determine whether an eligible designee must be appointed. It will also determine whether the eligible designee as QTA must take reasonable steps to collect delinquent contributions on behalf of the plan, taking into account the value of the plan assets involved, the likelihood of a successful recovery, and the expenses expected to be incurred in connection with collection. Whether the trustee's efforts to make this determination are ''reasonable and diligent'' will depend on the facts and circumstances of the case.

One commenter indicated that bankruptcy trustees may in some cases have difficulty obtaining records from the debtor's former management. Unfortunately, the Department's experience confirms that inadequate or missing records can be a common situation with abandoned plans, and this can impact the ability to determine whether delinquent contributions are owed. The Department recognizes that when a bankruptcy trustee is locating, updating, or recreating records to determine if any contributions are owed to the plan, they could incur a cost that will exceed the amount of any delinquent contributions. Consequently, the Department is of the view that a bankruptcy trustee will not have failed to make reasonable and diligent efforts to determine whether the plan is owed any contributions merely because the trustee reasonably concludes in good faith that it is impossible, or would involve significant cost to the plan in relation to the plan's total assets, to update or locate the necessary records to make the necessary determination. The bankruptcy trustee, after making such conclusion, may proceed for purposes of the obligation to collect delinquent contributions (discussed below) as if the plan is owed no more than a de minimis amount of contributions.

Second, at the time of the designation, the bankruptcy trustee must notify the eligible designee of its findings with respect to the amount of delinquent contributions. This notification applies regardless of whether the eligible designee is an asset custodian or an independent bankruptcy trustee practitioner, and it will enable the eligible designee to take appropriate action.

Third, the bankruptcy trustee must establish procedures for the eligible designee to have reasonable access to documents in the bankruptcy trustee's possession that may be needed to wind up the plan. There is no specific list of documents contemplated by this provision, but examples include payroll records, participant lists, plan documents, trust statements, or other similar records.

Fourth, the bankruptcy trustee is responsible for selecting and monitoring the eligible designee in accordance with ERISA section 404(a)(1)(A) and (B). One commenter expressed the view that chapter 7 bankruptcy trustees in general do not have expertise regarding the termination of ERISA plans. The

[20] See *U.S. Department of Justice, Executive Office for United States Trustees, Handbook for Chapter 7 Trustees, p. 2–1.* (October 1, 2012), for a discussion of eligibility to serve on a panel.

commenter argued that the chapter 7 trustee's obligation to the plan should terminate upon an eligible designee's appointment. As discussed above, the Department does not believe that terminating the chapter 7 bankruptcy trustee's obligation upon appointment of an eligible designee would be consistent with the structure designed by Congress. Accordingly, in the interim final rules, the duty to monitor the eligible designee is ongoing throughout the termination and winding up process until all plan assets are distributed.

Fifth, a reporting condition attaches to the bankruptcy trustee even after the eligible designee has terminated the plan. If the bankruptcy estate is still open after the eligible designee winds up the plan and the bankruptcy trustee, either directly or through monitoring and communicating with the eligible designee, discovers evidence of a fiduciary breach by a prior plan fiduciary (*e.g.,* the debtor) during this period, the bankruptcy trustee must notify the Department of this evidence. See discussion of paragraph (j)(7)'s reporting requirement below.

3. Winding up the Affairs of the Plan—§ 2578.1(d) and (j)(7)

(a) In General

The ''winding up'' steps for Chapter 7 ERISA Plans are in paragraphs (d) and (j)(7) of § 2578.1. These rules generally are the same as the rules for abandoned plans in the 2006 regulations, though there are two noteworthy differences.

The first major difference is with respect to delinquent contributions. These interim final rules require a QTA of a Chapter 7 ERISA Plan that is owed more than a de minimis amount of contributions (which would be determined based on both employer and employee contributions, combined) to take reasonable steps to collect delinquent contributions on behalf of the Chapter 7 ERISA Plan, taking into account the value of the plan assets involved, the likelihood of a successful recovery, and the expenses expected to be incurred in connection with collection. To avoid potential conflicts of interest between the bankruptcy trustee's duties to the bankruptcy estate and the bankruptcy trustee's duties to the Chapter 7 ERISA Plan, paragraph (j) of these interim final rules mandates that the bankruptcy trustee appoint an eligible designee when there is an obligation to collect delinquent contributions (*i.e.,* the amount of delinquent contributions is more than de minimis).

The second major difference is with respect to reporting evidence of a fiduciary breach that involves plan assets by a prior plan fiduciary. These interim final rules require any QTA to a Chapter 7 ERISA Plan to report to the Department any activities that the QTA believes may be evidence of fiduciary breaches by a prior plan fiduciary (*e.g.,* the debtor).

The justification for these two differences is that bankruptcy trustees, by virtue of their knowledge and control of the debtor's estate and ERISA plan, are in a position to:

(1) know of the liquidating sponsor's delinquent contributions and to facilitate the collection of these delinquencies, and

(2) discover evidence of fiduciary breaches by prior plan fiduciaries.

Paragraph (j)(5)(i) of § 2578.1 contains two alternative tests to define what is considered a de minimis amount of delinquent contributions, for purposes of the requirement to collect the contributions described above.

The first test focuses directly on the amount of contributions owed to the plan and provides that delinquent contribution amounts are de minimis if they are $2,000 or less. As noted above, this would be determined taking into account both delinquent employee and employer contributions. The Department estimates that $2,000 fairly represents what it typically would cost to review the bankruptcy case and to file a liquidated proof of claim, two steps ERISA's fiduciary standards would require in bankruptcy cases with delinquent contributions in need of protection. As such, the first test allows a plan owed only $2,000 or less in delinquent contributions to avoid potentially costly collection efforts.

The second test focuses on the ''net worth'' of the source of recovery. The test provides that delinquent contribution amounts greater than $2,000 are to be considered de minimis if the property from which to collect delinquent contributions is an amount (*i.e.,* a realizable value) that is equal to or less than $2,000 net of all enforceable liens and applicable exemptions. In effect, delinquent contributions (whatever the actual amount) are considered de minimis in amount when property in the bankruptcy case is likely equal to or less than the $2,000 de minimis amount. Although the plan has a legitimate claim against the bankruptcy estate, this test dispenses with the need to pursue a claim where it is reasonably evident there is insufficient property of value from which to collect delinquent contributions or to cover the plan's cost of filing a liquidated proof of claim. As part of the general request for comments in Section F of the preamble below, the Department is specifically asking for comment on the definition of ''de minimis'' in these interim final rules.

The de minimis rule in these interim final rules was added in response to comments expressing concern about the bankruptcy trustee's obligations to collect delinquent contributions. One commenter opposed placing any responsibility to collect delinquent contributions on chapter 7 bankruptcy trustees. The commenter noted that outside of the bankruptcy context, QTAs are obligated only to report known delinquencies to the Department, rather than taking steps to collect the delinquent contributions. The commenter also asserted that bankruptcy trustees do not generally have working knowledge of the prior business operations of the debtor.

Commenters also addressed whether the requirement to collect delinquent contributions creates a conflict of interest for chapter 7 bankruptcy trustees. One commenter asserted that bankruptcy trustees would face a conflict of interest in every case in which there is a reasonable likelihood that there are unpaid plan contributions due from the debtor or any other potential liability that the debtor (and now the bankruptcy estate) owes the plan. The commenter suggested, as one possibility, that a panel of chapter 7 trustees with special training could be appointed to liquidate ERISA plans. As another alternative, the commenter suggested that chapter 7 trustees should be permitted to provide the Department with a list of delinquencies they have reasonably discovered. On the other hand, a different commenter did not see any conflict between the role of the chapter 7 trustee and the obligation to collect delinquent contributions, as the commenter stated that the contributions due to ERISA plans that are attributable to workers' deferred wages are not the property of the estate under the Bankruptcy Code. The commenter further stated that because employer contributions are claims entitled to priority under the Bankruptcy Code, it is particularly important for the chapter 7 trustee to determine whether any delinquent employer contributions are owed to the plan. The commenter suggested that the chapter 7 trustee's obligations to collect delinquent employer contributions should be phrased as the trustee's obligation to pay amounts consistent with the payment priorities in section 507(a)(4) and (a)(5) of the Bankruptcy Code, and to file a claim for any excess amounts.

After consideration of these comments, the Department continues to

believe that the bankruptcy trustee's knowledge and control over the debtor's estate in combination with its obligations under BAPCPA justify the interim final rules' requirement to designate an eligible designee as the QTA to take reasonable steps to collect delinquent contributions of more than a de minimis amount. This approach is not based on the belief that chapter 7 bankruptcy trustees have access to information on the business' operation *prior to* the entity filing for bankruptcy, but rather on the bankruptcy trustee's existing control and access to current information. However, the obligation will not attach if the plan is owed no more than a de minimis amount of contributions. Further, the interim final rules in certain instances mandate that the bankruptcy trustee appoint an eligible designee to assume its responsibilities under the program with respect to the plan to avoid placing the bankruptcy trustee in conflict with the bankruptcy estate.[21] In such cases, the bankruptcy trustee would still be under an obligation to cooperate with the designee in the performance of those duties.

(b) Payment of Fees and Expenses

Because the winding up rules in the interim final rules are essentially the same for Chapter 7 ERISA Plans as they are for abandoned plans, the provisions governing payment of fees and expenses from plan assets also are essentially the same for both kinds of plans. The fee provisions generally provide that plan assets may be used to pay reasonable expenses of plan termination. What is reasonable is judged in light of industry rates for ordinary plan administration under ERISA.[22] Consequently, these provisions do not allow a bankruptcy trustee or eligible designee to charge attorney-level rates for plan administration activities of termination and winding up the plan.

Several commenters addressed this aspect of the proposal. One commenter expressed support for the proposal on the bases that that there should be no reason for chapter 7 trustees to charge higher fees for ordinary plan administration services and the fee limitation would help preserve the value of participants' retirement savings. Other commenters believed that chapter 7 bankruptcy trustees should not be limited to charging plan administration industry rates for their services, since their compensation would normally be higher for bankruptcy case administration. One commenter indicated the fee provisions would be a disincentive for chapter 7 bankruptcy trustees to take an active role in the termination and winding up activities. Another commenter asserted that chapter 7 trustee compensation is routinely reviewed by the presiding bankruptcy judge and the Department would be permitted to object in bankruptcy proceedings if it thought a trustee's compensation exceeded statutory limits.

The Department declines to make the specific changes requested by the commenters but has revised these interim final rules to include a limited exception to the general rule regarding fees. The limited exception would apply to services provided by the eligible designee in connection with the duty to collect delinquent contributions on behalf of the plan. Under the exception, the fees must be consistent with rates ordinarily charged by firms or individuals representing or assisting a bankruptcy trustee in performing similar collection services on behalf of an estate in a chapter 7 proceeding. This limited exception applies to activities such as filing proofs of claims, tracing assets, responding to objections, motion practice, and litigation on behalf of the plan, but it does not apply to determining whether the plan is owed contributions. The act of determining whether a plan is owed a contribution is a routine act of plan administration and is therefore covered under the general rule rather than the exception.

4. Rule of Accountability—§ 2578.1(j)(8)

The interim final rules retain the rule of accountability from the proposal. Paragraph (j)(8) provides that the bankruptcy trustee or eligible designee shall not, for themselves or the other, through waiver or otherwise, seek a release from liability under ERISA, or assert a defense of derived immunity (or similar defense) in any action brought against the bankruptcy trustee or eligible designee arising out of its conduct under the regulation.

The rule of accountability, as proposed, was based on the fact that the ERISA plan and its assets are not part of the estate. Accordingly, the rule merely sought to preserve this legal distinction by preventing bankruptcy trustees from using bankruptcy courts to insulate themselves from liability under ERISA for fiduciary breaches.[23]

The Department received several comments on the proposed rule of accountability. One commenter supported the proposed rule on the basis that paragraph (e) of § 2578.1 already limits ERISA liability for QTAs. Another commenter expressed concern that the rule of accountability would result in bankruptcy trustees' unwillingness to participate in the Abandoned Plan Program because the commenter believed the rule would interfere with the trustee's ability to seek bankruptcy court approval even when required to do so by the Bankruptcy Code. The commenter provided an example stating that bankruptcy trustees must seek bankruptcy court approval to hire appraisers, real estate brokers and auctioneers. The commenter recommended that the Department require that the Department be provided sufficient notice to object and have an opportunity to be heard regarding any proposed action in the bankruptcy court.

The Department does not believe the rule of accountability interferes with action required under the Bankruptcy Code. As stated in the preamble to the proposal, paragraph (j)(8) does not prevent a bankruptcy trustee from asking a court to resolve an actual dispute involving a plan or from obtaining an order required under the U.S. Bankruptcy Code. However, the rule of accountability would bar a trustee from seeking a ruling from a court for approval of its actions as a QTA. For example, as discussed above, the Department does not believe a bankruptcy court has jurisdiction to approve the payment to a professional from assets of the plan.

The Department continues to believe that the rule of accountability strikes the correct balance by permitting bankruptcy trustees to continue existing practices under the Bankruptcy Code while preventing them from seeking additional comfort from a bankruptcy court regarding compliance with ERISA as set forth in the Abandoned Plan Program. Beyond this principle, the Department did not adopt the commenter's suggestion to eliminate the rule of accountability in favor of the Department receiving notice and opportunity to be heard regarding any proposed action in the bankruptcy court.

One commenter expressed the view that the proposal did not go far enough in ensuring that bankruptcy courts do

[21] One commenter sought from the Department a list of approved QTAs; however, the Department does not keep such a list.

[22] Under § 2520.103–13, qualified termination administrators must file the Special Terminal Report for Abandoned Plans (STRAP). STRAPs contain total termination expenses paid by a plan and a separate schedule identifying each service provider and the amount received by that service provider, itemized by expense. STRAPs currently are available on the Department's website (see *https://www.askebsa.dol.gov/AbandonedPlanSearch/*).

[23] *See Kirschenbaum,* 777 F.3d at 597.

not relieve chapter 7 trustees from their obligations to plans. The commenter asked the Department to include additional information providing guidance on the manner in which the Department would prevent bankruptcy courts from discharging bankruptcy trustees from acting as fiduciaries with respect to the plans. As noted above, the Department believes it has struck an appropriate balance in this regard and therefore the Department has not included additional statements or information on this issue.

The Department seeks commenters' views on the construct of the rule of accountability in these interim final rules and whether specific changes are recommended.

C. Technical Comments Unrelated to the Expansion to Chapter 7 ERISA Plans

Several comment letters raised technical issues dealing with the Abandoned Plan Program in general, as opposed to Chapter 7 ERISA Plans specifically. The major comments are addressed below.

1. Removal of Statement of Investigation From the Notice of Plan Abandonment—§ 2578.1(c)(3)

Consistent with the proposal, these interim final rules remove the requirement that a QTA state whether it or any affiliate is, or in the past 24 months was, the subject of an investigation, examination, or enforcement action by the Department, the Internal Revenue Service, or the Securities and Exchange Commission concerning their conduct as a fiduciary or party in interest with respect to any ERISA-covered plan. QTAs were required to include this statement in the notice of plan abandonment furnished to the Department before a plan could be deemed terminated and wound up.[24]

Although such information alone would not bar a person from serving as a QTA, the statement served as a flagging mechanism to help the Department identify arrangements that potentially were not in the best interests of plan participants and beneficiaries. However, in the preamble to the 2012 proposal, the Department stated that generally it can determine from its own records whether a person is, or in the past 24 months was, the subject of such an investigation. Additionally, some otherwise qualified persons have expressed reluctance to serve as a QTA if they must affirm in a notice to the federal government that they or an affiliate are or were under such an investigation, examination, or enforcement action.[25]

The Department proposed to remove the requirement as unnecessary in light of other information sources available to the Department. The Department received two comments supporting the removal of the required statement of investigation. There were no comments opposing elimination of the requirement. Therefore, for the reasons stated in the proposal, the Department is removing the required investigation statement. In conjunction with removing the statement, the Department is removing a definition of the term ''affiliate'' from paragraph (h)(2) of § 2578.1 of the 2006 regulations, which was applicable only to the investigation statement. The generally applicable definition of the term ''affiliate'' in paragraph (h)(1) of § 2578.1 remains in effect.

2. Forfeitures/Small Accounts—§ 2578.1(d)(2)(ii)

With respect to applying the forfeiture provision in paragraph (d)(2)(ii) of section 2578.1 of the 2006 regulations, one commenter asked for clarification that a QTA can employ a de minimis exception for very small accounts where the cost of locating a participant would use up the account balance. The commenter noted that the general guidelines for winding up the affairs of a plan currently permit a QTA to treat as forfeited an account balance that is less than the estimated share of plan expenses allocable to the account.[26] The commenter asked for clarification or revision to the provision so that the rule would cover the estimated costs of locating the participant in addition to the estimated share of plan expenses allocable to the account.

Although forfeitures are permitted under these interim final rules, they are permitted only after a reasoned judgment that a participant's allocable share of anticipated plan expenses is likely to exceed their account balance. The Department's view is that it is not reasonable to assume that every participant with a small account balance will be missing. Therefore, allocating a predetermined search cost for participants whom the QTA has no reason to believe are missing would not ordinarily be considered reasonable for purposes of the forfeiture provision.

On the other hand, if a QTA were to determine that it must search for a specific participant—for example, if a Notice of Plan Termination sent to that participant was returned ''undeliverable''—the reasonable cost of searching for the participant would be a permissible plan expense and could be allocated entirely to the account of the missing participant in accordance with the principles in EBSA Field Assistance Bulletin 2003–03.[27] Accordingly, the Department determined that no changes are needed to the 2006 regulations, which leave such forfeiture determinations to a case-by-case determination based on the relevant facts and circumstances.

In this regard, the Department also seeks comment on the current provision in 2578.1(d)(2)(ii)(B) for allocating expenses to participant accounts in the absence of a governing plan document provision. The provision permits expenses to be allocated on a pro rata basis (proportionately in the ratio that each individual account balance bears to the total of all individual account balances) or per capita basis (allocated equally to all accounts). Do commenters believe that this flexibility is appropriate? For example, should the Department consider adding provisions to the regulation that would provide guidelines for the types of fees and circumstances that would be appropriate for per capita versus pro rata methods of allocation?

3. Distribution Alternatives/Missing Participants

Under the 2006 regulations, missing participant accounts were generally required to be distributed to individual retirement plans. In the case of a distribution by a QTA in which the amount to be distributed is $1,000 or less and that amount is less than the minimum amount required to be invested in an individual retirement plan product offered by the QTA to the public at the time of the distribution, the QTA may distribute a missing or non-responsive participant's account balance to:

(i) an interest-bearing federally insured bank or savings association account in the name of the participant or beneficiary;

[24] See paragraph (c)(3)(i)(C) of § 2578.1 in the 2006 final regulations.

[25] *See* 77 FR 74068.

[26] 29 CFR 2578.1(d)(1)(ii).

[27] Whether the cost of a particular search is reasonable depends on the facts and circumstances of the case. The Department, however, notes that a QTA should avoid search methods that cost more than the participant's account balance. *See* EBSA Field Assistance Bulletin 2014–01. For example, if the cost of a particular search method were to exceed the missing participant's account balance, the QTA should consider less costly search methods, such as those identified in FAB 2014–01. However, if the QTA reasonably determines that the cost of any of the available search methods would exceed the missing participant's account balance, the QTA may avoid a search and treat the account as forfeited under paragraph (d)(2)(ii) of section 2578.1.

(ii) the unclaimed property fund of the State in which the participant's or beneficiary's last known address is located; or

(iii) an individual retirement plan offered by a financial institution other than the QTA to the public at the time of the distribution.[28]

Commenters requested that the Department raise the $1,000 threshold to $5,000 and eliminate the condition that the amount be less than the minimum amount required to be invested in an individual retirement plan product offered by the QTA to the public at the time of the distribution. This would allow QTAs to distribute more accounts of missing or non-responsive participants to bank or savings accounts or State unclaimed property funds than under the current rule. According to the commenters, individual retirement plans (*e.g.,* IRAs) for very small balances are not profitable or widely available, and though some financial institutions offer IRAs with low minimum-balance requirements, they tend to do so only as a way to create and maintain relationships with customers who, unlike missing and non-responsive participants, are likely to regularly contribute to and grow their accounts. The commenters suggested that their recommended changes could increase the likelihood that more asset custodians would elect to serve as QTAs than under the current system, thereby eliminating more abandoned plans.

The Department is not adopting the commenters' suggestions at this time but seeks additional comment on the merits of various distribution options. The Department's regulations regarding default distributions and the Abandoned Plan Program historically have preferred IRAs to other distribution options for several reasons. A distribution that qualifies as an eligible rollover distribution from a qualified plan, which is handled by a trustee-to-trustee transfer into an individual retirement plan, will avoid immediate taxation. An eligible direct rollover results in the deferral of income tax, avoids 20 percent mandatory withholding, and avoids any 10 percent additional tax for early distributions that might otherwise apply.[29] Funds in the individual retirement plan continue to grow on a tax-deferred basis so that funds are not subject to federal income tax until distributed.[30]

In contrast, funds transferred to a bank/savings account or State unclaimed property fund generally are subject to income taxation, mandatory income tax withholding, and a possible additional tax for premature distributions. Moreover, any interest that accrues after the transfer would generally be subject to income taxation upon accrual.[31]

Another option is the Pension Benefit Guaranty Corporation's Missing Participants Program for Defined Contribution Plans pursuant to 29 CFR 4050.201–207 (PBGC Program). In Field Assistance Bulletin 2021–01, the Department provided a temporary enforcement policy under which it will not pursue violations under section 404(a) of ERISA against either responsible plan fiduciaries of terminating defined contribution plans or QTAs of abandoned plans when a missing or non-responsive participant's or beneficiary's account balances are transferred to the PBGC Program rather than to an IRA, certain bank accounts, or to a State unclaimed property fund, as specified in 29 CFR 2550.404a–3. The plan fiduciary or QTA must comply with the guidance in the FAB and act in accordance with a good faith, reasonable interpretation of section 404 of ERISA with respect to matters not specifically addressed in the FAB.

The Department is continuing that temporary enforcement policy under these interim final rules. As described below in its general request for comments in Section F, the Department requests comment on whether the PBGC Program gives missing participants a better chance than the other available distribution options of being reunited with their retirement savings and should therefore be formally incorporated into the Department's regulation at 29 CFR 2550.404a–3. The Department further requests comments on whether the PBGC Program should be used as a replacement for all other distribution options in the case of plans eligible for the PBGC Program.

Also, with respect to missing participants, the Department requests comments on the methods of providing the participant notices required under 2550.404a–3. One commenter asserted that notices provided before an involuntary cash out distribution are provided by certified mail. The Department seeks comment on whether this is the common way of providing notice in that context. The Department also seeks comment on whether QTAs are generally unable to rely on the electronic disclosure safe harbors in 29 CFR 2520.104b–1 because they are unable to satisfy the conditions for the safe harbors, and if so, whether additional guidance would be useful on the use of electronic disclosure technologies to provide notices under the Abandoned Plan Program regulations.

4. Distributions/Missing Participants/ IRAs Offered by Institutions Other Than the QTA—Paragraph (d)(2)(vii)(B)(1) of § 2578.1 & 2550.404a–3

One commenter asked for clarification on whether a QTA must accept distributions above $1,000 on behalf of missing or non-responsive participants or if they may instead distribute the account balance to an individual retirement plan offered by an institution other than the QTA.

Although the interim final rules generally contemplate that a QTA will designate itself as the provider of an individual retirement plan for such participants, this outcome is not required under the interim final rules (or the 2006 regulations). A QTA may distribute such account balances to an individual retirement plan offered by an institution other than the QTA, provided that the conditions of the interim final rules are satisfied, including those set forth in § 2550.404a–3. A QTA would be responsible as a fiduciary for the selection of this provider, as set forth in paragraph (e) of § 2578.1 (entitled ''Limited liability'').

5. Distributions/Deceased Participants—§ 2550.404a–3(d)(1)(v)

Sometimes a QTA will know that a missing participant whose account balance is greater than $1,000 is deceased and that there is no designated beneficiary, or the beneficiary also is deceased. In such circumstances, the 2006 regulations require the QTA to transfer the participant's account balance to an individual retirement plan even if it is unlikely that anyone will ever claim these benefits. The Department was advised that, in some cases, providers of individual retirement plans will not accept such distributions.

The 2012 proposal contained a special rule to address this situation. As proposed, the special rule would conditionally permit QTAs to transfer the account balances of decedents to an appropriate bank account or a state's unclaimed property fund, regardless of the size of the account balance, instead of to an individual retirement plan. The conditions allowed such a transfer if the QTA reasonably and in good faith finds that the participant and named

[28] Paragraphs 2578.1(d)(vii)(B)(1) and 2550.404a–3(d).

[29] *See* Code §§ 402(a), 3405(c), and 72(t).

[30] Depending on state law, state and local income taxes also may be subject to deferral.

[31] *See e.g.,* IRS Rev. Rul. 2020–24, Withholding and Reporting With Respect to Payments From Qualified Plans to State Unclaimed Property Funds.

beneficiary, if applicable, were deceased, and includes in the Final Notice filed with the Department the identity of the deceased participant (and beneficiary as applicable) and the basis for the finding.[32] The proposal's preamble solicited comments on whether the proposed conditions sufficiently safeguard the rights of participants and beneficiaries and asked in particular whether a QTA should be prohibited from making these transfers if the QTA has actual knowledge that a descendant of the deceased participant or beneficiary has a claim.

Commenters raised three general concerns about the workability of the special rule. First, QTAs often do not have beneficiary designation forms in their possession because the responsibility for maintenance of such forms was retained by the sponsor or delegated to another person who either cannot be located or no longer maintains possession of the records. Thus, in this scenario, QTAs cannot determine whether a living beneficiary exists. Second, often the participant's estate is designated (either affirmatively or by default) as the participant's beneficiary, and because estates cannot be ''deceased'' in the normal sense of that word, commenters indicated that the special rule should not be available in this circumstance. Third, QTAs sometimes are on notice that a descendant of the deceased participant or beneficiary claims to have a valid right under probate law and such descendant may or may not be a designated beneficiary under the plan terms and ERISA. In these circumstances, the commenters cautioned against outcomes that could lead to escheatment.

After considering the public comments, these interim final rules adopt the proposal's special rule permitting transfer of the deceased participant's account balance to an appropriate bank account or State unclaimed property fund in the name of the participant, even if the account balance exceeds $1,000, but with several modifications in response to the matters raised by the commenters intended to facilitate the termination and winding up of abandoned plans.

The first modification clarifies that the special rule is available for situations when, despite reasonable and good faith efforts, the QTA is unable to locate plan records that identify a beneficiary. See § 2550.404a–3(d)(1)(v)(A)(*2*). The interim final rules make clear that the special rule is available in these circumstances only if the QTA first conducts a reasonable search, consistent with the requirements of section 404 of ERISA, for the participant's beneficiary designation form.

Second, the special rule was expanded to cover situations when the beneficiary is the estate of the participant, without regard to whether the designation was affirmative or by default. See § 2550.404a–3(d)(1)(v)(B). However, availability of the special rule in these circumstances, depends on the QTA meeting certain conditions.

One condition is that the QTA first must make reasonable and good faith efforts to determine whether or not an estate exists before a transfer is permitted under the special rule. These interim final rules do not specify a method for satisfying this condition, as it will depend on the facts and circumstances of the particular case. However, the mere fact that an executor or administrator of an estate has not affirmatively contacted the QTA would not be sufficient evidence for the QTA to reach the requisite finding required by the condition.

Another condition is that the QTA must reasonably and in good faith find that it is unable to establish an individual retirement plan for the benefit of the estate of the participant. For example, this might occur if a QTA were to conclude that it is precluded by law from establishing an individual retirement plan for the benefit of an estate (as opposed to an individual) or if a bankruptcy trustee is unable after reasonable efforts to locate an individual retirement plan provider who will accept such a distribution.

Third, in response to concerns about potential litigation and competing claims by descendants and others, the special rule contains a new limitation—in no circumstance is the special rule available if the QTA has actual knowledge of any claims of a person purporting to have a right to all or part of the deceased participant's account. See paragraphs (d)(1)(v)(A)(*4*) and (B)(*2*) of § 2550.404a–3. For example, this might occur if the descendant of a deceased participant contacts the QTA in writing to assert a purported interest in the decedent's account balance. The Department agrees with the commenters that, in these circumstances, the QTA is on notice of the existence of a person who is or may become eligible to receive a benefit from the plan and that a transfer under the special rule may be inconsistent with or frustrate the rights of such person.

Finally, these interim final rules adopt the requirement that the QTA must document the relevant findings under the special rule and include this information in the Final Notice to the Department. See paragraph (d)(1)(v)(c) of § 2550.404a–3. This condition serves at least two purposes. First, it protects participants and beneficiaries by ensuring a determination of death is not premature and that reasonable and diligent efforts to find designated beneficiaries occurred. Second, it also prevents abuse of the special rule, limiting the number of transfers to bank or savings accounts or State unclaimed property funds.

6. QTA's Limited Liability—§ 2578.1(e)

Several commenters also asked the Department to make additional confirmations regarding the scope of liability of QTAs. One commenter asked whether the relief afforded by the Abandoned Plan Program regulations would extend to functions that are not addressed in the regulations, such as responding to domestic relations orders relating to benefits under the plan. The Department believes that it has constructed a regulatory framework that serves to minimize to the greatest extent possible the liability and exposure of QTAs who carry out their responsibilities in accordance with the provisions of the regulation. However, the limited liability provisions focus on the QTAs' activity winding up the affairs of the plan. For areas not addressed in the Abandoned Plan Program regulations, QTAs can look to the Department's more general guidance provided through advisory opinions, information letters, field assistance bulletins, interpretive bulletins, and other compliance assistance materials already available that address duties and obligations beyond the specific winding up affairs performed by QTAs.

Another commenter asked about the liability of the QTA after the abandoned plan is terminated and assets are distributed, particularly with respect to missing participants. The commenter urged the Department to clarify that a QTA that has substantially complied with the Abandoned Plan Program regulations would have no continuing liability for subsequent actions taken by the transferee of the assets. In this regard, paragraph (e)(ii) of § 2578.1 provides that the QTA is not responsible for monitoring a service provider selected in accordance with § 2550.404a–3, which provides a safe harbor for fiduciaries in connection with distributions from terminated

[32] A commenter sought additional guidance on what would constitute a valid basis for determining that a participant is deceased. The reasonable and good faith standard is a factual standard that would require evaluation of all the surrounding circumstances.

individual account plans. However, the Department cautions that it is unable to confirm that limited liability is available for ''substantial'' compliance. The Department is also unable to confirm in response to a similar comment that fiduciary relief would necessarily be available for certain activities of the QTA even if the QTA fails to meet every applicable requirement of the program. The extent of the QTA's liability would depend on the surrounding facts and circumstances.

7. Notices and Special Terminal Report—§ 2578.1(c)(3) and (j)(6), § 2578.1(d)(2)(ix), and § 2520.103–13

In response to a comment, the Department added spaces in the model notices to identify fiduciary breaches, as is required in connection with Chapter 7 ERISA Plans under these interim final rules. Specifically, the spaces were added in the Notification of Intent to Serve as a QTA to be used in connection with Chapter 7 ERISA Plans (Appendix C to part 2578) and in the Final Notice (Appendix E to part 2578). The commenter also asked why there is a Notice of Plan Termination in Appendix D part 2578 when the Appendix A to part 2550 appears to serve the same function of providing a model notice to be used for participant contributions. The Department agrees that the two model notices serve similar functions but the model notice in Appendix D to part 2578 contains a provision specific to the QTA context. The Department believes that it is most user friendly to provide the model notice for participant contributions as an appendix to part 2578 where other model notices that are specific to the Abandoned Plan Program are located. However, the Department made other minor and clarifying edits to the model forms included in the appendices to the Abandoned Plan Program regulations.

In response to comments, these interim final rules also streamline and update the process for filing notices and reports in two significant ways. First, the Special Terminal Report for Abandoned Plans (STRAP), *see* § 2520.103–13 is now a single, stand-alone form, as opposed to a collection of data from various parts of the Form 5500 Annual Return/Report of Employee Benefit Plan. Second, the interim final rules establish a new optional online method to file the STRAP and other notices, as opposed to the existing email or paper-based system.

With respect to the STRAP, the Department added language to 29 CFR 2520.103–13(b) to clarify that content requirements of the STRAP must be provided in accordance with the instructions for the STRAP posted on the Department's website. Pursuant to § 2520.103–13(b)(1), which authorizes the collection of plan information, the Department added a question to the STRAP to assist the Department in understanding the types of defined contribution plans that are terminated under the Abandoned Plan Program (*e.g.,* single-employer, multiemployer, multiple-employer, 401(k), 403(b) plans, etc.). These interim final rules add new paragraphs (b)(6) and (7) to § 2520.103–13, which ask for the total number of distributions and the number of distributions to missing participants included in that total. Because the Department often requests this information, these interim final rules add this information requirement to the STRAP to improve the efficiency of the program. In this regard, the Department is considering including a provision in the final rules that would either explicitly require QTAs to maintain records regarding the location of distributions of the accounts of missing participants, or that would require such information be provided in the STRAP. The Department seeks comment on these potential requirements as well as the extent to which QTAs currently maintain records on the location of these accounts and the length of time that the records are kept.

Since the STRAP is now a stand-alone form, the Department can no longer rely on the penalties and perjury statement embedded in the Form 5500 Annual Report. Accordingly, new paragraph (b)(8) adds a penalties and perjury statement to the content requirements of § 2520.103–13.

The Department also eliminated from the STRAP the requirements to report plan administrator identification information, whether the plan is collectively bargained, and the effective date of the plan. The Department concluded that information is not needed on the STRAP and should be available from prior Form 5500 filings for the plan or can be requested from the QTA to the extent the information is relevant in a particular case under the Abandoned Plan Program. The STRAP form and the instructions will be available on the Abandoned Plan Program section of EBSA's website.

The new optional online filing system—called the ''Abandoned Plan Program Online Filing System''—will provide a more efficient alternative method for QTAs to submit required notices to the Department because it will streamline the process. The Department will issue a press release when the online filing system becomes available. At that time, instructions for completing and filing notices and the STRAP through the online filing system will be available on the Abandoned Plan Program section of EBSA's website. The online system also will benefit the Department by enabling its staff to more efficiently receive, process, and review notices and STRAPs, which in turn will benefit QTAs and participants of the plans they are winding up. The Department expects that QTAs who opt to electronically submit notices and the STRAP will make fewer errors due to the web-based procedures and instructions that can ensure greater accuracy of data. The Department also expects transcription and other errors by the Department will be fewer because of the automated process that will occur when submissions are received electronically.

The new online filing system is voluntary under these interim final rules pending the adoption of the final rules. The Department is inclined to make the online filing system the exclusive method of filing Abandoned Plan Program notices and the STRAP. Accordingly, the Department is interested in receiving comments on whether it should make electronic filing mandatory as part of the final rules.

D. Internal Revenue Code Qualification Requirements

As it did in connection with the existing Abandoned Plan Program, the Department conferred with representatives of the Internal Revenue Service (IRS) regarding the qualification requirements under the Internal Revenue Code as applied to plans that are terminated pursuant to 29 CFR 2578.1, as modified by these interim final rules. The IRS has informed the Department that the modification in these interim final rules does not impact the correction principles currently memorialized in section 6.02(2)(e)(i) of Revenue Procedure 2021–30, 2021–31 IRB 172. Section 6.02(2)(e)(i) of Revenue Procedure 2021–30 provides that the permitted correction for a failure that results from the employer having ceased to exist, no longer maintaining the plan, or for similar reasons is to terminate the plan and distribute plan assets to participants and beneficiaries in accordance with standards and procedures substantially similar to those set forth in § 2578.1, applicable to individual account plans, provided that the following four conditions are met. First, the correction must comply with standards and procedures substantially similar to those set forth in § 2578.1. Second, the QTA, based on plan records located and updated in accordance with

§ 2578.1(d)(2)(i), must have reasonably determined whether, and to what extent, the survivor annuity requirements of sections 401(a)(11) and 417 of the Internal Revenue Code apply to any benefit payable under the plan and must take reasonable steps to comply with those requirements (if applicable). Third, each participant and beneficiary must have been provided a nonforfeitable right to their accrued benefits as of the date of deemed termination under § 2578.1(c)(1), subject to investment gains and losses between that date and the date of distribution. Fourth, participants and beneficiaries must receive notification of their rights under section 402(f) of the Internal Revenue Code. Notwithstanding the foregoing, as set forth in Section 6.02(2)(e)(i) of Revenue Procedure 2021–30, the IRS reserves the right to pursue appropriate remedies under the Internal Revenue Code against any party who is responsible for the plan, such as the plan sponsor, plan administrator, or owner of the business, even in its capacity as a participant or beneficiary under the plan.

The Department received several comments on the QTAs' responsibilities regarding the survivor annuity requirements under sections 401(a)(11) and 417 of the Internal Revenue Code. Paragraph (d)(2)(vii)(B)(2) of § 2578.1 states that with respect to distributions to participants or beneficiaries who fail to make an election as to the distribution of benefits, a QTA that determines the survivor annuity requirements apply may distribute benefits ''in any manner reasonably determined to achieve compliance with those requirements.'' This provision was included in the 2006 regulations after consultation with the IRS. Commenters on the 2012 proposal asked for additional guidance on reasonable compliance with the requirements. Commenters also indicated that QTAs may experience practical difficulties complying with the survivor annuity requirements due to lack of recordkeeping and lack of available annuity options for small amounts.

The Department believes that additional information and consultation with the IRS and the Department of the Treasury are needed, as the survivor annuity requirements are within their jurisdiction.[33] Accordingly, the Department requests additional comments on practical difficulties faced by QTAs complying with the survivor annuity requirements.

[33] *See* section 101 of Reorganization Plan No. 4 of 1978, 5 U.S.C. App.

E. Comments on Additional Expansion of, or Procedural Changes to, the Abandoned Plan Program

1. Expand Scope of Abandoned Plan Program to Plans of Sponsors in Liquidation or Receivership

A few commenters asked that the Abandoned Plan Program be expanded to cover a broader range of plans. For instance, one commenter requested that the Department consider expanding the 2006 regulations to cover plans of debtors in liquidation under chapter 11 of the Bankruptcy Code and plans of businesses in state receivership. Another commenter requested that the Department consider expanding the 2006 regulations to cover plans of failed insured depository institutions for which the FDIC as receiver acts as the plan sponsor and administrator.

With respect to plans of debtors in liquidation under chapter 11 of the Bankruptcy Code, the Department does not believe it has a basis for concluding that plans are effectively abandoned as a result of the sponsor's chapter 11 petition. Further, expanding the scope of the 2006 regulations to a broad range of receivership situations was not included in the proposal, and the Department does not believe it has an adequate public record regarding those other circumstances to ensure the Abandoned Plan Program is properly structured to address unique or different issues that may be presented. Accordingly, the Department is not expanding the scope of the program at this time, as requested by some commenters.

Nonetheless, based on the public comments submitted, greater expansion of the program may further the interests of participants and beneficiaries in such plans, and the Department believes exploration of such possible expansions of the Abandoned Plan Program is merited. As part of the general request for comments in Section F of the preamble below, the Department is specifically asking for comments on whether—and, if so, how—to extend the framework of the Abandoned Plan Program to cover plans whose sponsors are in bankruptcy under chapter 11 of the Bankruptcy Code, or receivership under the FDIC or other applicable federal or state law.

2. Expand Definition of QTA to Other Service Providers

Outside of the bankruptcy context, the program's definition of a QTA requires the QTA to be both eligible to serve as a trustee or issuer of an individual retirement plan, within the meaning of Internal Revenue Code section 7701(a)(37), and to hold assets of the abandoned plans. Several commenters asked the Department to expand the definition of a QTA so that recordkeepers and third-party administrators could serve that role. According to the commenters, these parties may be in a greater position than the asset custodian to have data that would be useful in the process of terminating a plan, and this expansion could increase the number of plans terminated under the Abandoned Plan Program. The commenters suggested the Department could limit the expansion to parties that are regulated by the Securities and Exchange Commission (SEC), noting that the Department had previously declined to expand the definition of a QTA to recordkeepers and third-party administrators due, in part, to lack of standards and oversight.[34] One commenter noted that in the case of a plan in which the employer serves as the trustee, there may technically not be an asset custodian that ''holds'' assets of the plan, rendering these plans ineligible to participate in the Abandoned Plan Program.

The Department is not persuaded by the commenters to expand the definition of a QTA as requested at this time. The Department continues to believe that regulatory oversight of the QTA is an important safeguard of abandoned plans. Further, the Department has concerns about service providers taking custody or control of plan assets under circumstances in which they have no authorization from the plan sponsor to do so. The existing rule, under which QTAs may engage, on

[34] 71 FR at 20821 (''Although the Department recognizes the critical role that recordkeepers, third-party contract administrators and other service providers to plans can and will play in the process of winding up the affairs of an abandoned plan, the Department nonetheless believes that, given the authority and control over plans vested in QTAs under the regulation, QTAs must be subject to standards and oversight that will reduce the risk of losses to the plans' participants and beneficiaries. In developing its criteria for QTAs, the Department limited QTA status to trustees or issuers of an individual retirement plan within the meaning of section 7701(a)(37) of the Code because the standards applicable to such trustees and issuers are well understood by the regulated community and the Department is not aware of problems attributable to weaknesses in the existing Code and regulatory standards for such persons. The Department believed that the Code and regulatory standards could be adopted for purposes of this regulation without imposing unnecessary costs and burdens on either plans or potential QTAs. The Department notes that, while commenters did propose varying procedures and criteria for defining QTA status, there was no consensus among the commenters as to what regulatory standards might be applicable to such persons. For these reasons, the Department is adopting the definition of 'qualified termination administrator' without change from the proposal.'').

behalf of the plan, such service providers as are necessary for the QTA to carry out its responsibilities, remains preferable.[35] However, the Department welcomes additional comment on this issue, and in particular, how the SEC's existing regulations applicable to recordkeepers and third-party administrators would protect the interests of the abandoned plans and their participants and beneficiaries.

3. Plans With Small Asset Balances/ Plans Funded Through Annuities

One commenter encouraged the Department to consider a limited and expedited QTA process for plans with only a small amount of total assets, such as a few thousand or even a few hundred dollars. In such cases, charging the plan to cover the costs of the Abandoned Plan Program may deplete some plans' remaining assets. The commenter envisioned that parties holding the assets could provide the Department with pre-termination reports with relevant information and the Department could then approve immediate distributions to remaining participants where such persons can be located. Commenters also raised the issue of plans that are funded through annuities and noted that there does not appear to be a mechanism for a QTA to be paid from the plan's assets when the annuity contract does not permit deduction of service fees.

While the Department is sympathetic to these concerns, it has not made any changes to these interim final rules in response. A change to the program to provide a special procedure for plans with few assets would require careful consideration of how best to protect the interests of the participants and beneficiaries in these plans and would benefit from additional public comment. Additionally, there does not appear to be a ready means of adapting the program to plans funded by annuities that do not permit deduction of service fees. The Department welcomes additional comment on these areas that may inform future regulatory activity.

4. Requested Procedure for Future Program Changes

One commenter asked whether the program could be structured in a way to allow changes to be implemented more frequently and more quickly. The commenter noted that the program is currently structured as a series of regulations and a prohibited transaction exemption, which require notice and opportunity for public comment before adoption of changes, while other programs such as the Department's Delinquent Filer Voluntary Compliance Program, are published as notices.

The Department believes that the structure of the existing program in the form of regulations and a prohibited transaction exemption benefits affected parties by providing certainty beyond what could be provided in the form of an enforcement policy or other type of notice. That structure does not prevent the Department from issuing opinions or other subregulatory guidance interpreting or clarifying the program's requirements.

F. Request for Comments

The Department believes that the interim final rules address the major comments raised with respect to the 2012 proposal and improve the program, especially with respect to the inclusion of Chapter 7 ERISA Plans. However, as noted above, the Department acknowledges that the 2012 proposal was published more than 10 years ago and that these regulations have been published as interim final rules with a request for comments. This approach will enable bankruptcy trustees to begin taking advantage of the voluntary termination and winding up procedures almost immediately, while allowing for comments and possible further improvement of the Abandoned Plan Program. Although the Department will accept comments from interested persons on all aspects of these interim final rules in accordance with the instructions for submitting comments in the **ADDRESSES** section of this document, the Department specifically invites comments on the following subjects.

First, comments are requested on the two alternative tests in paragraph (j)(5)(i) of section 2578.1 for determining whether contributions are de minimis in amount, including whether the $2,000 threshold is sufficiently protective of plan participants and beneficiaries and whether the Department should add a provision for indexing that threshold for inflation. Any comments suggesting that the $2,000 threshold is too low should suggest a specific dollar threshold with supporting analysis.

Second, the Department requests comment on the requirement for eligible designees to take reasonable steps to collect delinquent contributions on behalf of the plan, taking into account the value of the plan assets involved, the likelihood of a successful recovery, and the expenses expected to be incurred in connection with collection, and the expansion of the definition of eligible designee to include an independent bankruptcy trustee practitioner.

Third, comments are requested on whether, and if so, how, to extend the framework of the Abandoned Plan Program to cover plans whose sponsors are in liquidation under chapter 11 of the Bankruptcy Code, state receivership, or receivership under the FDIC. Commenters on this issue are encouraged to explain the need for such an extension for each type of liquidation or receivership, including the anticipated costs and benefits to affected parties.

Fourth, the Department is interested in comments on whether it should incorporate the PBGC Program into 29 CFR 2578.1. On December 22, 2017, PBGC established the PBGC Program to hold retirement benefits for missing participants and beneficiaries in most terminated defined contribution plans and to help those participants and beneficiaries find and receive those benefits. See 29 CFR 4050.201–207. The PBGC cites multiple benefits of the PBGC Program, including: (1) benefits of any size can be transferred to the PBGC; (2) periodic active searches by the PBGC increase the likelihood of connecting missing participants with their benefits; (3) benefits are not diminished by ongoing maintenance fees or distribution charges; (4) transferred amounts grow with interest (at the applicable Federal mid-term rate); (5) transfers to the PBGC Program result in the deferral of income tax, avoid the 20 percent mandatory withholding, avoid any 10 percent additional tax, and grow on a tax deferred basis, and (6) lifetime income options are available for balance transfers that are non-de minimis ($7,000 after December 31, 2023). As stated in the preamble to the PBGC's final rule adopting the PBGC Program, the Department intended to look into what changes are needed to its safe harbor regulation (29 CFR 2550.404a–3) so that transfers to the PBGC by terminating individual account plans would be eligible for relief under the safe harbor.[36] Thereafter, in FAB 2021–01, the Department announced a temporary enforcement policy under which it will not pursue violations under section 404(a) of ERISA against either responsible plan fiduciaries of terminating defined contribution plans or QTAs of abandoned plans in connection with the transfer of a missing or non-responsive participant's or beneficiary's account balance to the

[35] 2578.1(d)(2)(iv).

[36] 82 FR 60800. Previously, the PBGC Program covered only the PBGC-insured single-employer defined benefit plans as part of the standard termination process. The PBGC Program was expanded to cover defined contribution plans (*e.g.,* 401(k) plans), and certain other defined benefit plans that terminate on or after January 1, 2018.

PBGC in accordance with the PBGC Program rather than to an IRA, certain bank accounts, or to a State unclaimed property fund, as specified in 29 CFR 2550.404a–3. Such plan fiduciaries and QTAs must comply with the guidance in the FAB and act in accordance with a good faith, reasonable interpretation of section 404 of ERISA with respect to matters not specifically addressed in the FAB. As noted above, the Department is continuing the temporary enforcement policy under these interim final rules and is specifically interested in stakeholder views on whether the PBGC Program should be formally incorporated into the Department's regulation at 29 CFR 2550.404a–3 as an alternative to other available distribution options for missing or non-responsive participants and beneficiaries or perhaps as a replacement for plans that meet the requirements of the PBGC Program for all other distribution options for such persons. The goal of the change would be to give missing participants a better chance than under other distribution options of being reunited with their retirement savings. For example, the PBGC Program would establish a known, centralized repository that would preserve a participant's account balance and, where the account exceeds certain threshold amounts ($7,000 after December 31, 2023), permit missing participants to elect distribution in the form of an annuity to ensure lifetime income as well as in a lump sum. The PBGC Program also could reduce administrative burdens in particular on abandoned defined contribution plans, especially with respect to small accounts, accounts of deceased participants, and accounts subject to the Internal Revenue Code's joint and survivor annuity rules.

To the extent commenters support the transfer of the accounts of missing and non-responsive participants to the PBGC under the Abandoned Plan Program, the Department is interested in comments addressing additional changes to 29 CFR 2578.1 that would facilitate such transfers. For example, should the Department consider modifying the definition of a QTA to allow third party administrators (TPAs) or other entities that do not currently satisfy paragraph (g) of 29 CFR 2578.1 to act as a QTA solely for the purposes of winding up an abandoned plan by transferring all of the accounts of missing and non-responsive participants to the PBGC? [37] If so, what conditions should be imposed on TPAs or other entities? For example, should the TPA or other entity be required to demonstrate in the notice of intent to serve as QTA that it has the authority under existing documentation to direct the custodian to pay distributions to participants and beneficiaries?

Fifth, to the extent commenters do not support replacing all the current distribution options under 29 CFR 2550.404a–3 with the PBGC Program, the Department is interested in comments on whether the current Abandoned Plan Program options for distributions to State unclaimed property funds should be expanded. The Department has engaged over time with a range of stakeholders on issues surrounding missing and unresponsive participants, including State unclaimed property funds. See, *e.g.,* GAO Report 19–88 ''Federal Action Needed to Clarify Tax Treatment of Unclaimed 401(k) Plan Savings Transferred to States (January 2019); and Report of the ERISA Advisory Council, ''Voluntary Transfers of Uncashed Checks from ERISA Plans to State Unclaimed Property Programs'' (November 2019). The ERISA Advisory Council concluded that State unclaimed property funds ''have a number of features that may decrease the risk of the funds being depleted by account fees and increase the likelihood that [m]issing [p]articipants will be reunited with their lost retirement savings.'' [38] Following the ERISA Advisory Council report, the National Association of Unclaimed Property Administrators [39] proposed that the Department develop a uniform, nationwide regulation for the voluntary transfer to unclaimed property funds of uncashed lump sum distribution checks, cash outs of $5,000 or less pursuant to Internal Revenue Code § 411(a)(11), required minimum distributions, and plan mandated lump sum distributions at normal retirement age.[40] The Department is interested in comments on the merits of such a limited voluntary option being added to the Abandoned Plan Program.[41]

Sixth, the Department is interested in whether 29 CFR 2550.404a–3 should be amended to permit the distribution of Code section 403(b) individual annuity contracts and Code section 403(b)(7) individual custodial accounts. A terminating Code section 403(b) plan must distribute all accumulated benefits to all participants and beneficiaries as soon as administratively practicable after termination of the plan.[42] The IRS has addressed terminating 403(b) plans in Revenue Ruling 2011–7, 2011–10 IRB 534, including issues related to delivery to participants or beneficiaries of a fully paid individual annuity contract or an individual certificate evidencing fully paid benefits under a group annuity contract. Revenue Ruling 2020–23, 2020–47 IRB 1028, involved a terminating Code section 403(b) plan with 403(b)(7) custodial accounts where the plan made in-kind distributions of individual custodial accounts (ICAs) to those participants and beneficiaries who did not affirmatively elect a distribution or a direct rollover to an eligible retirement plan.[43] The Department is

[37] Paragraph (g) defines a *qualified termination administrator as an entity that* (1) is eligible to serve as a trustee or issuer of an individual retirement plan, within the meaning of section 7701(a)(37) of the Internal Revenue Code, and (2) holds assets of the plan that is found abandoned pursuant to paragraph (b).

[38] ERISA Advisory Council Report—*Voluntary Transfers of Uncashed Checks from ERISA Plans to State Unclaimed Property Programs* (November 2019) at p. 39.

[39] The National Association of Unclaimed Property Administrators (NAUPA) is a network of the National Association of State Treasurers (NAST) which leads and facilitates collaboration among administrators in their efforts to reunite unclaimed property with the rightful owner. NAUPA's membership consists of unclaimed property administrators representing the governments of all 50 states, the District of Columbia, the Commonwealth of Puerto Rico, U.S. Virgin Islands, several Canadian provinces, and Kenya.

[40] The Department has issued opinions and other guidance that takes the position that section 514 of ERISA preempts State unclaimed property laws that require a plan fiduciary of an ERISA employee pension benefit plan to distribute or transfer the accrued benefits of a missing participant to the state. Advisory Opinion 94–41A (Dec. 7, 1994); Advisory Opinion 79–30A (May 14, 1979); Advisory Opinion 78–32A (Dec. 22, 1978); Information Letter to Mr. Willis E. Sullivan, III Chair, Drafting Committee to Revise Uniform Unclaimed Property Act National Conference of Commissioners on Uniform State Laws (March 3, 1995).

[41] The Department also notes that the SECURE 2.0 Act of 2022 requires the Department to establish and maintain an online searchable database, to be called the Retirement Savings Lost and Found, that will, among other things allow individuals to search for the contact information of the administrators of certain types of retirement plans, with respect to which the individual is or was a participant or beneficiary. As it moves forward with the development of the Retirement Savings Lost and Found, the Department intends to evaluate its impact on the Abandoned Plan Program.

[42] 26 CFR 1.403(b)–10(a)(1).

[43] Section 110 of Division O of the Further Consolidated Appropriations Act, 2020, Public Law 116–94, 133 Stat. 2534 (2019) known as the Setting Every Community Up for Retirement Enhancement Act of 2019 (SECURE Act), directed the Secretary of the Treasury to issue guidance providing that the plan administrator or custodian of a terminating Code section 403(b) plan with 403(b)(7) custodial accounts may distribute an ICA in kind to a participant or beneficiary of the plan. Section 110 also provided that the in-kind distribution of the ICA would be tax-deferred, similar to the treatment of fully paid individual annuity contracts under Rev. Rul. 2011–7, until amounts are actually paid to the participant or beneficiary. Contemporaneous with the publication of Rev. Rul. 2020–23, the IRS published Notice 2020–80, 2020–47 IRB 1060

interested in comments on whether the Abandoned Plan Program should expressly address distribution of an annuity contract or an ICA to a missing or non-responsive participant or beneficiary compared to a default rollover to an individual retirement plan or a transfer to the PBGC in the case of a Code section 403(b) plan with 403(b)(7) custodial accounts.[44] The Department is also seeking comments on whether the distribution framework set forth in 29 CFR 2550.404a–3 is consistent with Revenue Rulings 2011–7 and 2020–23.

Seventh, the Department is interested in comments on whether provisions should be added to the Abandoned Plan Program specifically addressing participants in abandoned plans for whom benefits were previously forfeited pursuant to Treasury regulation § 1.411(a)–4(b)(6), because the plan could not locate them. That regulation provides that a right to a benefit is not treated as forfeitable ''merely because the benefit is forfeitable on account of the inability to find the participant or beneficiary to whom payment is due, provided that the plan provides for reinstatement of the benefit if a claim is made by the participant or beneficiary for the forfeited benefit.''

G. Regulatory Impact Analysis

1. Background and Need for Regulatory Action

As stated earlier in this preamble, this document contains amendments to three 2006 regulations that facilitate the termination of, and distribution of benefits from, individual account pension plans that have been abandoned by their sponsoring employers. The primary effect of the amendments is to extend the 2006 regulations to Chapter 7 ERISA Plans. The amendments also make other minor, unrelated changes to the 2006 regulations to include: (1) the elimination of the requirement that QTAs state in a notice to the Department whether they, or any affiliate are, or in the past 24 months were, the subject of an investigation, examination, or enforcement action by the Department, the Internal Revenue Service, or the Securities and Exchange Commission concerning their conduct as a fiduciary or party in interest with respect to any ERISA-covered plan; and (2) conditional permission for QTAs to transfer the account balances of certain decedents to an appropriate bank account or a state's unclaimed property fund regardless of the size of the account balance. The need for the amendments is explained in detail above in this preamble, as well as the preamble to the 2012 proposal.

The Department has examined the effects of these amendments as required by Executive Order 12866,[45] Executive Order 13563,[46] the Congressional Review Act,[47] the Paperwork Reduction Act of 1995,[48] the Regulatory Flexibility Act,[49] section 202 of the Unfunded Mandates Reform Act of 1995,[50] and Executive Order 13132.[51]

2. Executive Orders 12866 and 13563 Statement

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing and streamlining rules, and of promoting flexibility. It also requires federal agencies to develop a plan under which the agencies will periodically review their existing significant regulations to make the agencies' regulatory programs more effective or less burdensome in achieving their regulatory objectives. The Department identified the amendments to the 2006 regulations as part of a retrospective regulatory review project consistent with the principles of Executive Order 13563. The changes will improve the overall efficiency of the program established under the 2006 regulations, increase its usage, and substantially reduce burdens and costs on bankruptcy trustees (or their designees) terminating the plans of sponsors in chapter 7 liquidation, the plans of bankrupt sponsors, and the participants in these plans.

Under Executive Order 12866, ''significant'' regulatory actions are subject to the requirements of the executive order and review by the Office of Management and Budget (OMB). As amended by Executive Order 14094[52] entitled ''Modernizing Regulatory Review,'' section 3(f) of the executive order 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 $200 million or more (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) creating 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 legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case. OMB has determined that these amendments are a significant regulatory action under section 3(f)(4) of E.O. 12866.

3. Affected Entities

The group of entities affected by the amendments consists of affected abandoned plans as defined under the 2006 regulations, Chapter 7 ERISA Plans newly eligible to utilize the abandoned plan rules, and the financial firms and bankruptcy trustees who serve as QTAs.

Based upon Department records it is estimated that approximately 1,340 plans identify as abandoned plans to the Department each year; these plans average approximately 6.4 participants per plan, for a total of roughly 8,549 participants (1,340 plans × 6.38 participants per plan). The Department assumes this level of utilization will continue and uses it as an estimate for the group of plans wound up annually under the 2006 regulations.

The Department used the following information and approach to estimate the additional plan load created by the amendments. There are three key data points required to estimate the impact of the regulations: (1) bankruptcy rates, (2) defined contribution plan prevalence (offer rates), and (3) utilization rates.

requesting comments on the application of the annuity and survivor provisions of section 205 of ERISA, in connection with in-kind distribution of an ICA from a terminating § 403(b) plan.

[44] The PBGC Program will accept a transfer from a terminating or abandoned Code section 403(b) plan with 403(b)(7) custodial accounts, but not from a 403(b) annuity contract plan. *See* 29 CFR 4050.201(a)(2) and fn. 8 of the preamble of PBGC's final missing participant rule at 82 FR 60800, 60802 (2017).

[45] Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993).

[46] Improving Regulation and Regulatory Review, 76 FR 3821 (Jan. 21, 2011).

[47] 5 U.S.C. 804(2) (1996).

[48] 44 U.S.C. 3506(c)(2)(A) (1995).

[49] 5 U.S.C. 601 *et seq.* (1980).

[50] 2 U.S.C. 1501 *et seq.* (1995).

[51] Federalism, 64 FR 43255 (Aug. 10, 1999).

[52] 88 FR 21879 (April 6, 2023).

The Department assumes that the plan sizes will be similar to that experienced under the 2006 regulations; therefore, data regarding the offer rates are restricted to smaller establishments (defined as under 50 employees). Finally, the source for bankruptcy rates, *uscourts.gov*, reports in the aggregate; therefore, the Department's estimates use this aggregate rate, which may differ from that of certain subgroups, such as smaller firms.

Data from *uscourts.gov* for chapter 7 bankruptcies filed between 2018 and 2022 support an estimate of 12,900 chapter 7 cases being filed annually.[53] Census Bureau data on county business patterns [54] indicate that approximately 75 percent of establishments are small, and BLS data [55] show the Defined Contribution plan offer rate for small firms is around 48%. Due to the lack of available data regarding the rate of utilization by defined contribution plans during chapter 7 proceedings, the Department has constructed estimates at 10, 25, and 100 percent utilization rates. The estimated costs are shown in Table 1 below.

TABLE 1—SUMMARY OF ESTIMATED COST OF AMENDMENTS AT SELECTED PLAN UTILIZATION RATES

Component of Interim Final Rule	Estimated cost change at a 10% utilization rate	Estimated cost change at a 25% utilization rate	Estimated cost change at a 100% utilization rate
Additional Plans	466	1,166	4,662
Additional Participants	2,973	7,439	29,744
Notice to Plan Sponsor (to locate by QTAs)	.....	.....	.....
Notice to DOL (on plan abandonment/program utilization)	$51,088	$127,831	$511,103
Bankrupt Plans (Court Order) (Trustee appt)	11,540	28,875	115,451
Notice to Participants	38,781	97,037	387,980
Final Notice	14,004	35,040	140,101
Chapter 7 ERISA Plans (Fiduciary Breach) (to DOL as part of abandonment notice)	5,938	14,859	59,410
Special Terminal Report (to DOL)	187,383	461,591	1,801,906
Safe Harbor	.....	.....	.....
Class Exemption Familiarization	.....	.....	.....
	308,735	765,232	3,015,950

Note: Costs include costs for labor and materials & postage where relevant.

A 10 percent utilization rate yields an estimate of approximately 1,800 plans and 11,500 participants in total, after the amendment.[56] Using a 100 percent utilization rate results in an estimate of roughly 6,000 plans with 38,300 participants using the program each year.[57] Using a utilization rate of 25 percent in the calculations, which the Department will use as the estimate here, results in approximately 1,200 additional plans (with roughly 7,500 participants [58] utilizing the Abandoned Plan Program due to the amendments, bringing the estimated annual utilization numbers to 2,500 plans with 16,000 participants).[59]

The Department estimates that approximately 1,031 QTAs (including bankruptcy trustees) will act to establish user accounts to use the online filing system with the Department, which is described in section C.7 of this preamble.

4. Benefits

a. Benefits of Expanding Regulations to Chapter 7 ERISA Plans

The amendments to the 2006 regulations provide critical guidance that will encourage the orderly and efficient termination of Chapter 7 ERISA Plans and distribution of account balances, thereby increasing the retirement income security of participants and beneficiaries in such plans. Absent the standards and procedures set forth in the amendments, some bankruptcy trustees may lack the necessary guidance to properly terminate Chapter 7 ERISA Plans and distribute benefits to participants and beneficiaries. Specifically, the amendments clarify the bankruptcy trustee's (or, as applicable, the eligible designee's) obligations as QTA with respect to updating plan records, calculating account balances, selecting, and monitoring service providers, distributing benefits, and paying fees and expenses.

The Department believes that providing this guidance and allowing bankruptcy trustees to serve or designate others to serve as QTAs will lead to administrative cost savings for bankruptcy trustees who choose to use these interim final rules. The Department has not quantified these benefits because it does not have sufficient information regarding the characteristics of Chapter 7 ERISA Plans. The Department expects that bankruptcy trustees will decide to use the termination and winding up procedures in the interim final rules based on their individual assessment of whether it would be more cost effective to terminate a plan under or outside of the regulatory safe harbors.

One of the potential administrative cost savings that would result from the amendments is that Chapter 7 ERISA Plans would file one streamlined

[53] A weighted average of the past 5 years data is calculated for years 2018–2022 as: (13,906 × 30%) + (13,678 × 25%) + (14,324 × 20%) + (10,803 × 15%) + (8,131 × 10%) ≈ 12,890. The weights were chosen to account for the distortion during the Covid–19 pandemic. *https://www.uscourts.gov/statistics-reports/analysis-reports/bankruptcy-filings-statistics/bankruptcy-statistics-data.*

[54] *https://data.census.gov/cedsci/table?q=private%20sector%20establishments%20by%20size&tid=CBP2019.CB1900CBP.*

[55] BLS data accessed 08/22/2022 *https://data.bls.gov/cgi-bin/srgate,* lesser of series (NBU22000000000227372 & NBU220000000000001 27372) for 2021 data.

[56] 1,800 ≈ 1,806 = [(12,900 CHPT 7) × (48% small plans offering DC plans) × (75.3% proportion of small plans) × (10% abandonment rate of plans with firms in CHPT 7)] + (1,340 plans currently using the program); 11,500 participants ≈ 11,522 = 1,806 plans × 6.38 participants.

[57] 6,000 ≈ 6,002 = [(12,900 CHPT 7) × (48% small plans offering DC plans) × (75.3% proportion of small plans)] + (1,340 plans currently using the program); 38,300 participants ≈ 38,293 = 6,002 plans × 6.38 participants per plan.

[58] 1,200 ≈ 1,166 = (12,900 CHPT 7) × (48% small plans offering DC plans) × (75.3% proportion of small plans) × (25% abandonment rate of plans with firms in CHPT 7).

[59] 2,506 = (1,340 plans currently using the program) + (1,166 new plans); 16,000 participants ≈ 15,988 = 2,506 plans × 6.38 participants.

termination report at the end of the winding up process in lieu of filing Form 5500 Annual Return/Reports. Additionally, Chapter 7 ERISA Plans that are not eligible for the small plan audit waiver of 29 CFR 2520.104–46 (generally, plans with fewer than 100 participants) would avoid incurring costly audit fees that otherwise would diminish plan assets.

Other benefits of the amendments include enhancements to retirement security of individuals in Chapter 7 ERISA Plans because of the requirements that QTAs, with certain exceptions: (1) take reasonable steps to collect delinquent contributions on behalf of the plan, taking into account the value of plan assets involved, the likelihood of a successful recovery, and the expenses expected to be incurred in connection with the collection of contributions, and (2) report to the Department delinquent contributions (employer and employee) owed to the plan, and any activity believed to be evidence of other fiduciary breaches by a prior plan fiduciary that involve plan assets.

Removing barriers to winding down the plans may result in preserving the value of, and hastening access to, the participants' assets. A potential benefit is the reduction of the likelihood of becoming a missing participant. As time passes, record accuracy can degrade as former employees move. In these instances, funds may be transferred into a low yielding account meant to preserve the assets. By preventing the employee from becoming a missing participant and giving them access to their funds, plan participants can invest the assets according to their risk tolerances. Each of these benefits affect the value of the participants' assets in a positive manner.

b. Benefits of Other Amendments to the 2006 Regulations

Benefits Associated with Amendment to Safe Harbor for Distributions from Terminated Individual Account Plans (29 CFR 2550.404a–3): This section provides a safe harbor under which plan fiduciaries (including QTAs) of terminated individual account plans can directly transfer a missing or non-responsive participant's account balance directly to appropriate investment vehicles in the participant's name. An exception exists for account balances of $1,000 or less, which may be transferred to an interest-bearing, federally-insured bank or savings association account or to the unclaimed property fund of a state in cases where certain conditions are satisfied. As stated above in this preamble, § 2550.404a–3 is being amended to conditionally permit QTAs to transfer the account balances of certain decedents to an appropriate bank account or a state's unclaimed property fund, regardless of the size of the account balance. The amendments would remove an obstacle to greater usage of the Abandoned Plan Program by eliminating the need to establish individual retirement plans for the account balances of known deceased participants with no known, living named beneficiary that are over $1,000 when it is unlikely that anyone will claim the funds in such plans.

c. Benefits Associated With Amendment To Eliminate Statement of Past or Present Investigations

As stated above in this preamble, § 2578.1 is being amended to remove the statement of past or present investigations in the notice of plan abandonment from the QTA to the Department (see § 2578.1(c)(3)(i)(B)). The Department believes that, at present, this statement is unnecessary and may even discourage firms to serve as QTAs, undermining the use of the Abandoned Plan Program. The Department holds this belief because EBSA's Office of Enforcement is easily able to run searches to determine whether potential QTAs are under investigation by the Department. By encouraging more potential QTAs to wind up abandoned plans in accordance with the Abandoned Plan Program regulations, the Department believes abandoned plan terminations will occur more efficiently, and more participants and beneficiaries of abandoned plans will gain access to their benefits.

5. Costs

The Department estimates that the cost associated with these interim final rules, at a 25 percent utilization rate by firms in bankruptcy would total approximately $765,232, as shown in Table 1 above. These costs would result from the estimated 1,166 Chapter 7 ERISA Plans that decide to use the termination and winding up procedures in the interim final rules and the estimated 1,031 QTAs (including bankruptcy trustees) that choose to create accounts with the Department's online filing system in order to file their STRAPs electronically. These costs are quantified and discussed in more detail in the Paperwork Reduction Act section, below.

6. Cost Savings

As discussed above, the costs associated with these interim final rules total approximately $870,059. Participation in the Abandoned Plan Program is burden reducing in that it relieves participating plans from their obligation to comply with Form 5500 Annual Reporting requirements and Summary Annual Report requirements for the period of bankruptcy and/or program utilization.

The Department estimates that the average period of bankruptcy proceedings for Chapter 7 ERISA Plans is 2.5 years. Therefore, absent the Abandoned Plan Program, the 1,166 Chapter 7 ERISA Plans estimated to participate in the Abandoned Plan Program each year would be obligated to file an average of 3.5 Form 5500–SFs and 3.5 accompanying Summary Annual Reports—one Form 5500–SF filing and accompany Summary Annual Report for each year the Chapter 7 ERISA Plan was in bankruptcy proceedings and/or abandoned, and one terminal Form 5500–SF filing and accompanying Summary Annual Report.[60] These Chapter 7 ERISA Plans would each also need to apply for an EFAST2 credential in order to electronically file Form 5500–SFs.[61]

The Department estimates that the approximate cost per plan to file a Form 5500–SF is $302, the cost for similarly sized plans to create and distribute a Summary Annual Report is approximately $87, and the cost to apply for an EFAST2 credential is approximately $39.[62] Therefore, the total cost savings in Form 5500 filing relief is $1,234,391 (1,166 Chapter 7 ERISA Plans × 3.5 Form 5500–SF filings × $302), the total cost savings in Summary Annual Report requirements relief is $355,326 (1,166 Chapter 7 ERISA Plans × 3.5 Summary Annual Reports × $87), and the total cost savings from not having to apply for EFAST2 credentials is $45,575 (1,166 plans × $39).[63]

[60] The Department notes that this figure is an average for burden calculation purposes. A relatively equal number of plans would file three and four Form 5500–SFs and accompanying Summary Annual Reports.

[61] EFAST2 credentials are issued on an individual basis and are valid indefinitely unless a period of three calendar years passes without use. The Department assigns the cost of credentialling to each case to provide a conservative estimate. It constitutes roughly 7 percent of the total cost of filing per plan.

[62] Estimates are based on time estimates in supporting statements which are available at *reginfo.gov* associated with control numbers 1210–0040 and 1210–0110 and wage rate estimates maintained by EBSA. For a description of the Department's methodology for calculating wage rates, see *https://www.dol.gov/sites/default/files/ebsa/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-july-2017.pdf.*

[63] Totals differ due to rounding.

The total cost savings is $1,635,292 ($1,234,391 + $355,326 + $45,575). When compared against the $765,232 in new costs for Chapter 7 ERISA Plans, the net cost savings resulting from this expansion of the Abandoned Plan Program is $870,059 annually.

H. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), the Department solicited comments concerning the information collection requirements (ICRs) included in the December 12, 2012 proposed amendments to the 2006 regulations at 77 FR 74063 and the proposed amendments to the class exemption PTE 2006–06 at 77 FR 74055. At the same time, the Department also submitted the ICR to OMB in accordance with 44 U.S.C. 3507(d). The Department received seven comments on the proposal. One commenter raised several questions about the model notices associated with 29 CFR 2578.1. The Department responded to the commenter, including by making some changes to the model notices, as discussed above in section C.7. of the preamble. Another commenter suggested that in the context of the potential expansion of the program to include FDIC receivers, the FDIC receiver should not be required to review ERISA section 408(b)(2) notices and prepare and distribute ERISA section 404(a)(5) notices detailing fees and costs for a plan that is being terminated. As the Department did not expand the program to include FDIC receivers as part of these interim final rules, this comment was not addressed.

The changes made by these interim final rules affect the existing OMB Control Number 1210–0127. A copy of the ICR for OMB Control Number 1210–0127 may be obtained by contacting the PRA addressee listed in the following sentence or at *www.RegInfo.gov.* For additional information, contact: James Butikofer, Office of Research and Analysis, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, Room N–5718, Washington, DC 20210; or *ebsa.opr@dol.gov.* The OMB will consider all comments that they receive on or before June 17, 2024. Comments and recommendations for the information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

The Department assumes that most of the tasks that will be undertaken by QTAs to terminate and wind up plans are the same as those required in normal plan administration, such as calculating or distributing benefits, and therefore are not accounted for as burden in this analysis because they are either part of the usual business practices of plans or have already been accounted for in ICRs for other statutory and regulatory provisions under title I of ERISA.

The interim final rules require QTAs to furnish a series of notices and a report in the process of terminating and winding up plans. For instance, before winding up a plan, the QTA (other than the QTA of a Chapter 7 ERISA Plan) must make reasonable efforts to locate or communicate with the plan sponsor, such as by sending a notice to the last known address of the plan sponsor notifying the sponsor of the intent to terminate and wind up the plan and allowing the sponsor an opportunity to respond. Following the QTA's finding of abandonment, or when there is an entry of an order for relief for a Chapter 7 ERISA Plan, the QTA must file with the Department a notice of plan abandonment that contains core information about the plan and the person electing to be the QTA. The QTA then must furnish to each participant or beneficiary a notice with information about the termination, the person's account balance, and requesting that such person elect a form of distribution. Upon terminating and distributing the assets of the plan, the QTA must file a final notice to the Department stating that the plan has been terminated and all the plan's assets have been distributed. In conjunction with the final notice, the QTA must file the Special Terminal Report for Abandoned Plans (STRAP) in accordance with instructions published by the Department. The STRAP may be filed electronically using the Department's online filing system when it becomes available. If a QTA chooses to use the online filing system, the QTA will be required to create an account with the Department. The Department estimates the burden of these notices and reports as a cost burden to the plan because the QTA uses plan assets to pay for the notices and STRAP. The only burden reported as hour burden is the burden incurred by plan administrators themselves for compliance with the safe harbor for non-abandoned plans, which are information collection requests (ICRs) subject to the PRA. The hour and cost burden associated with these ICRs are summarized in Table 2 below.

TABLE 2—PRA HOUR AND COST BURDEN

Component of interim final rule	Incremental cost burden associated with amendments (a)	Incremental hours burden associated with amendments (b)	Cost burden associated with existing regulations (c)	Hours burden associated with existing regulations (d)	Total cost burden (a + c)	Total hours burden (b + d)
Notice to Plan Sponsor (to locate by QTAs)	$0	0	$8,442	335	$8,442	335
Notice to DOL (on plan abandonment/plan utilization)	0	1,360	0	1,563	0	2,924
Chapter 7 ERISA Plans (Court Order) (Trustee appt)	0	292	0	0	0	292
Notice to Participants	47,238	539	54,287	620	101,526	1,159
Final Notice	0	389	0	447	0	835
Chapter 7 ERISA Plans (Fiduciary Breach) (to DOL as part of abandonment notice)	0	136	0	0	0	136
Special Terminal Report (to DOL)	0	3,949	0	4,539	0	8,488
Safe Harbor	0	0	44,816	42,026	44,816	42,026
Class Exemption Familiarization	0	583	0	670	0	1,253
Total	47,238	7,248	107,545	50,200	154,783	57,449

Note: Cost burdens include costs for materials and postage where relevant.

1. Notice to Plan Sponsor

This provision only applies to plans that are not Chapter 7 ERISA Plans therefore the changes to this component are caused by updating inputs and not by any changes to the rule. The Department estimates that for each of these estimated 1,340 plans, a QTA would require 10 minutes of clerical staff time at an hourly labor rate of $63.45 to complete the information on the plan sponsor notice, and five minutes of an accountant's time at an hourly labor rate of $116.86 to review and sign the notice.[64] This results in approximately 223 hours of clerical staff time with an associated cost burden of $14,171 (223 hours × $63.45 per hour) and 112 hours of an accountant's time with an associated cost burden of $13,049 (112 hours × $116.86 per hour).[65]

These notices are sent by a method requiring acknowledgement of receipt. Therefore, mailing costs include $6.25 for postage and email receipt of delivery. The mailing costs include paper and print costs of five cents per page for the one-page notice. Therefore, the materials and mailing costs are estimated to be $8,442 for the 1,340 notices (1,340 notices × ($6.25/notice + $0.05/notice)). These components result in a total estimated cost associated with the 2006 regulations notices to plan sponsors of $35,662.

2. Notice of Plan Abandonment to the Department

The Department estimates that for each of the estimated 2,506 plans participating in the Abandoned Plan Program (1,340 non-Chapter 7 ERISA Plans and 1,166 Chapter 7 ERISA Plans), a QTA may utilize 30 minutes of a clerical worker's time at an hourly rate of $63.45 to fill in the needed information on the notice. The Department also assumes that 40 minutes of an accountant's time with an hourly rate of $116.86 will be required to prepare required plan information, and to review and sign the forms. This results in about 1,253 hours (2,506 plans × 30 minutes) of clerical staff time with an equivalent cost burden of $79,503 (1,253 hours × $63.45 per hour), and 1,671 hours (2,506 plans × 40 minutes) of an accountant's time with an equivalent cost burden of $195,234 (1,671 hours × $116.86 per hour) for a total estimated equivalent cost burden of $274,737. Based upon recent filing trends between QTAs and the Department, 100 percent of plans are expected to furnish the information electronically at de minimis cost.

3. Bankruptcy Trustee's Appointment—Chapter 7 ERISA Plans

For an estimated 1,166 Chapter 7 ERISA Plans, an additional cost would be incurred for the QTA to attach to the notice of plan abandonment a copy of the order entered in the case reflecting the bankruptcy trustee's appointment to administer the case. The Department estimates that it will take 10 minutes of an accountant's time to prepare the required statement and collect required documents and five minutes of clerical time to make required copies. This is expected to impose an additional burden of approximately 194 hours (1,166 plans × 10 minutes) for accountants with an equivalent cost of $22,710 (194 hours × $116.86 per hour). For the clerical professionals, the burden is estimated at 97 hours (1,166 plans × 5 minutes) with an equivalent cost of $6,165 (97 hours × $63.45 per hour). This results in a labor cost of approximately $28,875 to produce the notice of bankruptcy trustee's appointment.

The rule requires the order entered in the case reflecting the bankruptcy trustee's appointment to be included with the notice of plan abandonment. Based upon recent filing trends between QTAs and the Department, 100 percent of plans are expected to furnish the information electronically at de minimis cost.

4. Notice to Participants and Beneficiaries

Data provided by EBSA's Office of Enforcement show that the average abandoned plan contains 6.38 participants. As stated previously, the Department estimates that approximately 1,340 abandoned plans will apply each year. This covers approximately 8,549 participants (1,340 plans × 6.38 participants per plan). In light of the expansion of the 2006 regulations to cover plans of sponsors in chapter 7 liquidation, the Department estimates that there will be a roughly 90 percent increase in applications, bringing the total number of filings up to 2,506.[66] Assuming that Chapter 7 ERISA Plans have roughly the same number of participants as abandoned plans, the total number of participants affected would be approximately 15,988 (2,506 plans × 6.38 participants per plan).

The Department estimates that for each of the estimated 2,506 terminating plans, a QTA will utilize 15 minutes of an accountant or similar professional's time to prepare and review the plan's notices to participants and beneficiaries. Clerical staff will spend two minutes per participant preparing and mailing the notices. This results in approximately 533 hours (2,506 plans × 6.38 participants per plan × 2 minutes per participant) of clerical staff time with an equivalent cost of $33,815 (533 hours × $63.45 per hour) and 627 hours (2,506 plans × 15 minutes per plan) of an accountant or similar professional's time with an associated cost burden of approximately $73,213 (627 hours × $116.86 per hour). This results in an estimated cost of approximately $107,028 for labor to produce the notices to participants and beneficiaries.

The Department estimates that this notice, on average, is two pages and must be furnished to the last known address of each participant or beneficiary. The Department received comments in response to the 2012 proposal suggesting that postage cost estimates for this component should reflect certified mail. The Department has increased its estimates of the postage costs accordingly but is also seeking comments above on the use of certified mail. The mailing and material costs for paper notices are estimated to be $6.35 per mailing (2 pages × $.05 per page + $6.25 postage). The Department estimates that 15,988 participants (2,506 plans × 6.38 participants per plan) will receive the notice by mail, creating a mailing cost burden of $101,526. Combining this cost with the labor to produce the notices, the total cost is estimated at approximately $208,554.

5. Final Notice

The Department estimates that for each of the estimated 2,506 terminating plans, a QTA will utilize 10 minutes of an accountant's time to review the forms in the Final Notice to the Department. Clerical staff will spend, on average, 10 minutes per plan preparing and mailing the notices. This results in about 418 hours (2,506 plans × 10 minutes) of clerical staff time with an equivalent cost of $26,501 (418 hours × $63.45 per hour) and 418 hours of an accountant's time (2,506 plans × 10 minutes) with an equivalent cost of $48,809 (418 hours × $116.86 per hour). This results in an estimated labor cost of approximately $75,309 to produce the Final Notices.

[64] For a description of the Department's methodology for calculating wage rates, see *https://www.dol.gov/sites/default/files/ebsa/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-july-2017.pdf.*

[65] Burden estimates presented in the text are rounded to the nearest hour; however, in calculating equivalent costs, unrounded burden estimates are used.

[66] The estimation of additional plans is explained in detail in Section 3 Affected Plans of this document.

Based upon recent filing trends between QTAs and the Department, 100 percent of plans are expected to furnish the information electronically at de minimis cost.

6. Reporting Requirement for Prior Plan Fiduciary Breaches

As discussed earlier in this preamble, the amendments would require QTAs of Chapter 7 ERISA Plans (whether they are bankruptcy trustees or eligible designees) to report to the Department delinquent contributions (employer and employee) owed to the plan, and any activity that the QTA believes may be evidence of other fiduciary breaches by a prior plan fiduciary that involve plan assets. When applicable, this information must be reported in conjunction with the filing of the Final Notice or Notice of Plan Abandonment. If, after the completion of the winding up of the plan, the bankruptcy trustee, in administering the debtor's estate, discovers additional information that it believes may be evidence of fiduciary breaches by a prior plan fiduciary that involve plan assets, the bankruptcy trustee must report such activity to the Department in a time and manner specified in instructions developed by the Department.

While the Department has no basis for estimating the percentage of arrangements that will be subject to each of these reporting provisions, the Department assumes for purposes of this analysis that a report will be required for 20 percent of Chapter 7 ERISA Plans. Thus, given an estimated 1,166 Chapter 7 ERISA Plans, the Department estimates that 233 plans will need to report such information. The Department anticipates that 30 minutes of a financial professional's time and five minutes of clerical time will be required to prepare and process the information. The Department therefore estimates that the burden for plans will be approximately 117 hours of an accountant's time (233 plans × 30 minutes) at an equivalent cost of $13,626 (233 hours × $116.86 per hour) and 19 hours of clerical time (233 plans × 5 minutes) at an equivalent cost of $1,233 (19 hours × $63.45 per hour). This results in an estimated labor cost of approximately $14,859 to produce and distribute notices of fiduciary breaches to the Department.

The Department assumes that the reporting of this information will be made with the Notice of Plan Abandonment or Final Notice; based upon recent filing trends between QTAs and the Department, 100 percent of plans are expected to furnish the information electronically at de minimis cost.

7. Special Terminal Report for Abandoned Plans (29 CFR 2520.103–13)

The Department estimates that it will take plans 3.25 hours to file the STRAP in accordance with the instructions on the Department's website. It is assumed that an accounting professional working at a cost of $116.86 per hour will perform this task resulting in a burden of 8,145 hours (2,506 plans × 3.25 hours) and an equivalent cost of $951,766 (8,145 hours × $116.86 per hour).

The Department assumes all STRAPs will be submitted electronically once the Department's online filing system becomes available. To achieve this, QTAs (including bankruptcy trustees) will need to set up user accounts the first time they serve as a QTA and use the Department's new online submission system. The Department estimates that 1,031 QTAs (including bankruptcy trustees) will set up user accounts each year. It is assumed that a compensation and benefits professional will take 20 minutes to complete this task resulting in a burden of 344 hours (1,031 QTAs × 20 minutes) and an equivalent cost of $40,298 (344 hours × $117.26 per hour). Combining these figures results an estimated labor cost of $992,065 to prepare and submit the STRAPs.

8. Safe Harbor for Distributions From Terminated Individual Account Plans (29 CFR 2550.404a–3)

The PRA analysis also includes the burden associated with the notice to participants as required under ''The Safe Harbor for Distributions from Terminated Individual Account Plans.'' To meet the safe harbor, fiduciaries of terminating plans (other than abandoned plans) must furnish a notice to participants and beneficiaries informing them of the plan's termination and the options available for distribution of their account balances. The Department estimates that 1,136,306 participants and beneficiaries will receive notices from 24,897 plan sponsors. The Department estimates that a benefits manager will spend approximately 10 minutes per plan preparing the notices. This results in 4,150 hours of benefits manager burden (24,897 plans × 10 minutes) at an equivalent cost of $559,892 (4,150 hours × $134.93 per hour). Clerical professionals will spend, on average, two minutes per notice preparing and distributing the 1,136,306 notices. This results in 37,877 hours of clerical burden (1,136,306 notices × 2 minutes) at an equivalent cost of $2,403,287 (37,877 hours × $63.45 per hour). It is assumed that 5.8 percent of participants will receive the notice by first class mail and 94.2 percent will receive the notice electronically at de minimis cost. The Department estimates that mailing the notices will produce a cost burden of $44,816 (1,136,306 participants × 5.8 percent receiving mailed notices) × ($0.63 for postage + ($0.05 per page × 1 page)).[67] Thus, the notice required under the Safe Harbor for Distributions from Terminated Individual Account Plans produces a total hour burden of 42,026 hours at an equivalent cost of $2,963,179 and a total cost burden of $44,816 for materials and postage. These costs are borne by non-Abandoned Plans and are not attributable to the amendments expanding the 2006 regulations to Chapter 7 ERISA Plans.

9. Abandoned Plan Class Exemption, PTE 2006–06

PTE 2006–06 permits a QTA of an individual account plan that has been abandoned by its sponsoring employer to select itself or an affiliate to provide services to the plan in connection with the termination of the plan, and to pay itself, or an affiliate, fees for these services, provided that such fees are consistent with the conditions of the exemption. The exemption also permits

[67] The Department estimates approximately 94.2% of participants receive disclosures electronically under the combined effects of the 2002 electronic disclosures safe harbor and the 2020 electronic safe harbor. The Department estimates that 58.2% of participants will receive electronic disclosures under the 2002 safe harbor. According to the National Telecommunications and Information Agency (NTIA), 40.0% of individuals age 25 and over have access to the internet at work. According to a Greenwald & Associates survey, 84.0% of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt-out of electronic disclosure that are automatically enrolled (for a total of 33.6% receiving electronic disclosure at work). Additionally, the NTIA reports that 40.4% of individuals age 25 and over have access to the internet outside of work. According to a Pew Research Center survey, 61.0% of internet users use online banking, which is used as the proxy for the number of internet users who will affirmatively consent to receiving electronic disclosures (for a total of 24.7% receiving electronic disclosure outside of work). Combining the 33.6% who receive electronic disclosure at work with the 24.7% who receive electronic disclosure outside of work produces a total of 58.2%. The remaining 41.8% of participants are subject to the 2020 safe harbor. According to the 2019 American Community Survey, 86.6% of the population has an internet subscription. The Department estimates that 0.5% of electronic disclosures will bounce back and will need to be sent a paper disclosure. Accordingly, for the 41.8% of participants not affected by the 2002 safe harbor, 86.1%, or an additional 36.0% (41.8% × 86.1%), are estimated to receive electronic disclosures under the 2020 safe harbor. In total, the Department estimates that 94.2% (58.2% + 36.0%) would receive electronic disclosures.

a QTA to: (1) designate itself or an affiliate as a provider of an individual retirement plan or other account; (2) select a proprietary investment product as the initial investment for the rollover distribution of benefits for a participant or beneficiary who fails to make an election regarding the disposition of such benefits; and (3) pay itself or its affiliate in connection with the rollover.

Currently, PTE 2006–06 and the accompanying Abandoned Plan Program regulations do not cover plans of sponsors involved in chapter 7 bankruptcy proceedings. In this regard, bankruptcy trustees do not meet the definition of QTA as set forth in the existing Abandoned Plan Program regulations and the class exemption. The amendments expand the definition of QTA to include bankruptcy trustees and certain persons designated by them to act as QTAs in terminating and winding up the affairs of abandoned plans. The Department believes that the amendments to the Abandoned Plan Program regulations and PTE 2006–06 will incentivize many bankruptcy trustees to carry out plan terminations consistent with ERISA, which will ultimately benefit participants and beneficiaries of such plans by ensuring abandoned plans are terminated in an orderly and cost-effective manner.

Compliance with the amendments to the Abandoned Plan Program regulations is a condition of the amendment to the class exemption; therefore, the costs and benefits that would be associated with complying with the amendment to the class exemption have been described and quantified in connection with the economic impact of the regulatory amendments. In its current form, PTE 2006–06 requires, among other things, that fees and expenses paid to the QTA and an affiliate in connection with the termination of an abandoned plan are consistent with industry rates for such or similar services, and are not in excess of rates ordinarily charged by the QTA (or affiliate) for the same or similar services provided to customers that are not plans terminated pursuant to the Abandoned Plan Program regulations, if the QTA (or affiliate) provides the same or similar services to such other customers. The amended class exemption provides an exception for services provided in connection with the duty to collect delinquent contributions on behalf of the plan. The exception judges what is reasonable in light of industry rates ordinarily charged by firms or individuals representing or assisting a bankruptcy trustee in performing similar collection services on behalf of an estate in a chapter 7 proceeding. The class exemption, in its current form, also requires that QTAs ensure that the records necessary to determine whether the conditions of the exemption have been met are maintained for a period of six years, so that they may be available for inspection by any account holder of an individual retirement plan or other account established pursuant to this exemption, or any duly authorized representative of such account holder, the Internal Revenue Service, and the Department. Banks, insurance companies, and other financial institutions that provide services to abandoned plans and their participants and beneficiaries are required to act in accordance with customary business practices, which would include maintaining the records required under the terms of the class exemption, both in its current form. Accordingly, the recordkeeping burden attributable to the amendment will be handled by the QTA and is expected to be small. However, there is an additional cost to directing this process. The Department assumes that a supervisor must devote time to each case to study the details of the individual plan, determine whether there have been any violations, and ensure that these details are properly incorporated into the notices. Assuming all QTAs will take advantage of the exemption, the hour burden attributable to supervisory duties for QTAs of abandoned plans (including familiarization costs for new QTAs) is expected to be one half hour for each QTA, or 1,253 hours (2,506 plans × 30 minutes). Assuming a financial manager's wage rate of $190.63 per hour, this supervisory cost is expected to total $238,859 ($190.63 per hour × 1,253 hours).

Also, in certain limited circumstances, the current exemption PTE 2006–06 requires QTAs to provide the Department with a statement under penalty of perjury that services were performed and a copy of the executed contract between the QTA and a plan fiduciary or plan sponsor. The Department does not include burden for these requirements as the burden is small, and the statement and contract can be included with other notices sent to the Department.

Below is a summary of the burden:

Type of Review: Revision of Existing Collection.

Agency: Employee Benefits Security Administration, Department of Labor.

Title: Notices for Terminated Abandoned Individual Account Plans.

OMB Number: 1210–0127.

Affected public: Individuals or households; business or other for- profit; not-for-profit institutions.

Respondents: 28,434.

Responses: 1,162,551.

Frequency of Response: One time.

Estimated Total Burden Hours: 42,026.

Cost Burden: $2,963,179.

I. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) applies to most Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*). Unless an agency certifies that such a rule will not have a significant economic impact on a substantial number of small entities, section 603 of the RFA requires the agency to present a final regulatory flexibility analysis at the time of the publication of the rulemaking describing the impact of the rule on small entities. Small entities include small businesses, organizations, and governmental jurisdictions. For purposes of analysis under the RFA, the Department considers a small entity to be an employee benefit plan with fewer than 100 participants.[68] The basis of this definition is found in section 104(a)(3) of ERISA, which permits the Secretary of Labor to prescribe simplified annual reports for welfare benefit plans that cover fewer than 100 participants. While some large employers may have small plans, in general, small employers maintain most small plans. Thus, the Department believes that assessing the impact of these final regulations on small plans is an appropriate substitute for evaluating the effect on small entities. The definition of small entity considered appropriate for this purpose differs, however, from a definition of small business that is based on size standards promulgated by the Small Business Administration (SBA) (13 CFR 121.201) pursuant to the Small Business Act (15 U.S.C. 631 *et seq.*). The Department requested comments on the appropriateness of this size standard at the proposed rule stage and received no adverse responses.

The Abandoned Plan Program is a voluntary program intended to provide a cost effective, streamlined option for winding up abandoned plans. The Department believes that these amendments will expand usage of the Abandoned Plan Program and help to preserve the assets of Chapter 7 ERISA

[68] The Departments consulted with the Small Business Administration Office of Advocacy in making this determination, as required by 5 U.S.C. 603(c) and 13 CFR 121.903(c) in a memo dated June 4, 2020.

Plans, thereby maximizing benefits ultimately payable to participants and beneficiaries and improving economic efficiency.

Essentially all abandoned plans are assumed to be small plans. Therefore, the more detailed discussion earlier in the preamble on the costs of the amendments is applicable to this analysis of costs under the RFA. As discussed previously in the RIA section, the costs associated with the amendments to the Abandoned Plan Program total approximately $765,232 and affect approximately 1,166 plans in a given year. This is an average of $656.29 per plan. This cost is net of the savings described in section 6 above, which are expected to be roughly $1,400 per plan attributable to the STRAP replacing multiple years of reporting requirements.

The most recent Private Pension Plan Bulletin estimates that there were 257,699 plans with less than 10 participants in 2020, which is the size group most consistent with historical utilization trends. Comparing this group with the estimated 1,166 plans that may use the program annually indicates that they represent less than 0.5 percent of very small defined contribution plans which is not a substantial number of the small plans affected.[69]

The Department also examined the costs relative to the participant asset balances in the group of plans assumed to be most likely to utilize the program. For a participant in the smallest plans measured by the number of participants and average per participant account balance, the roughly $103 per participant cost represents, on average, a 2.4 percent reduction in their account balance, which is not a significant impact. The distributions of participant account balance reductions are presented in Table 3 below, by plan size, for all small plans.

TABLE 3—COST AS A PERCENTAGE OF BALANCE

[Per participant]

Plan size	10th percentile	25th percentile	Median	Mean	75th percentile	90th percentile
0–9	2.37	0.51	0.14	0.06	0.05	0.02
10–19	2.18	0.59	0.20	0.11	0.08	0.04
20—29	2.18	0.63	0.23	0.13	0.10	0.06
30—39	2.26	0.66	0.25	0.14	0.11	0.06
40—49	2.16	0.66	0.26	0.15	0.12	0.07
50—59	2.13	0.66	0.27	0.16	0.13	0.07
60—69	2.09	0.67	0.27	0.17	0.13	0.07
70—79	2.13	0.69	0.28	0.17	0.14	0.07
80—89	2.06	0.68	0.28	0.17	0.14	0.08
90—99	1.91	0.66	0.28	0.17	0.14	0.07

Source: 2020 Private Pension Plan Bulletin Research File, EBSA.
Notes: Excludes plans reporting no assets and no participants.

Due to the small number of small plans involved and relatively low cost per plan and participant, the Assistant Secretary of the Employee Benefit Security Administration hereby certifies under 5 U.S.C. 605 that this rule will not have a significant economic impact on a substantial number of small entities

J. Congressional Review Act

This amendment is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and will be transmitted to the Congress and the Comptroller General for review. The interim final rule is not a ''major rule'' as that term is defined in 5 U.S.C. 804, because it is not likely to result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, or Federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

K. Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), the rule does not include any Federal mandate that will result in expenditures by state, local, or tribal governments in the aggregate of more than $100 million, adjusted for inflation, or increase expenditures by the private sector of more than $100 million, adjusted for inflation.

L. Federalism Statement

Executive Order 13132 (August 4, 1999) outlines fundamental principles of federalism and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have substantial direct effects on the States, the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. This rule does not have federalism implications because it has no 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. Section 514 of ERISA provides, with certain exceptions specifically enumerated, that the provisions of Titles I and IV of ERISA supersede any and all laws of the States as they relate to any employee benefit plan covered under ERISA. The requirements implemented in the rule do not alter the fundamental provisions of the statute with respect to employee benefit plans, and as such would have no implications for the States or the relationship or distribution of power between the national government and the States.

List of Subjects

29 CFR Part 2520

Accounting, Employee benefit plans, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2550

Employee benefit plans, Employee Retirement Income Security Act, Employee stock ownership plans, Exemptions, Fiduciaries, Investments, Investments foreign, Party in interest, Pensions, Pension and Welfare Benefit Programs Office, Prohibited transactions, Real estate, Securities, Surety bonds, Trusts and Trustees.

[69] Employee Benefits Security Administration, *Private Pension Plan Bulletin: Abstract of 2020,* Table B1, (2022).

29 CFR Part 2578

Employee benefit plans, Pensions, Retirement.

For the reasons set forth in the preamble, the Department of Labor amends 29 CFR chapter XXV as follows:

PART 2520—RULES AND REGULATIONS FOR REPORTING AND DISCLOSURE

■ 1. The authority citation for part 2520 is revised to read as follows:

Authority: 29 U.S.C. 1021–1025, 1027, 1029–31, 1059, 1134 and 1135; and Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012). Sec. 2520.101–2 also issued under 29 U.S.C. 1132, 1181–1183, 1181 note, 1185, 1185a–b, 1191, and 1191a–c. Sec. 2520.101–5 also issued under 29 U.S.C. 1021(f). Sec. 2520.101–6 also issued under 29 U.S.C. 1021(k). Sec. 2520.103–13 also issued under 29 U.S.C. 1023. Secs. 2520.102–3, 2520.104b–1, 2520.104b–3, and 2520.104b–31 also issued under 29 U.S.C. 1003, 1181–1183, 1181 note, 1185, 1185a–b, 1191, and 1191a–c. Secs. 2520.104b–1 and 2520.107 also issued under 26 U.S.C. 401 note, 111 Stat. 788.

■ 2. Revise § 2520.103–13 to read as follows:

§ 2520.103–13 Special terminal report for abandoned plans.

(a) *General.* The terminal report required to be filed by the qualified termination administrator pursuant to § 2578.1(d)(2)(viii) of this chapter shall be in the form published by the Department in the Abandoned Plans section of the Employee Benefits Security Administration's website and shall contain the information set forth in paragraph (b) of this section. Such report shall be filed in accordance with the method of filing set forth in paragraph (c) of this section and at the time set forth in paragraph (d) of this section.

(b) *Contents.* The terminal report described in paragraph (a) of this section shall contain the following information in accordance with the instructions to the terminal report published by the Department in the Abandoned Plans section of the Employee Benefits Security Administration's website:

(1) Identification information concerning the plan, the qualified termination administrator, and, if applicable, the bankruptcy trustee.

(2) The total assets of the plan as of the date the plan was deemed terminated under § 2578.1(c) of this chapter, prior to any reduction for termination expenses and distributions to participants and beneficiaries.

(3) The total termination expenses paid by the plan and an identification of each service provider and amount received, itemized by expense.

(4) The total distributions made pursuant to § 2578.1(d)(2)(vii) of this chapter and a statement regarding whether any such distributions were transfers under § 2578.1(d)(2)(vii)(B) of this chapter.

(5) The identification, fair market value and method of valuation of any assets with respect to which there is no readily ascertainable fair market value.

(6) The total number of distributions.

(7) The number of distributions to missing participants included in the total number of distributions reported in paragraph (b)(6) of this section.

(8) A statement that the information being provided in the report is true and complete based on the knowledge of the person electing to be the qualified termination administrator, and that the information is being provided by the qualified termination administrator under penalty of perjury.

(c) *Method of filing.* The terminal report described in paragraph (a) of this section shall be filed in accordance with instructions pertaining to terminal reports of qualified termination administrators published by the Department in the Abandoned Plans section of the Employee Benefits Security Administration's website.

(d) *When to file.* The qualified termination administrator shall file the terminal report described in paragraph (a) of this section within two months after the end of the month in which the qualified termination administrator satisfies the requirements in § 2578.1(d)(2)(i) through § 2578.1(d)(2)(vii), and § 2578.1(j)(7) as applicable, of this chapter.

(e) *Limitation.* (1) Except as provided in this section, no report shall be required to be filed by the qualified termination administrator under part 1 of title I of ERISA for a plan being terminated pursuant to § 2578.1 of this chapter or by a bankruptcy trustee described in § 2578.1(j)(3) of this chapter or an eligible designee described in § 2578.1(j)(4) of this chapter.

(2) Filing of a report under this section by the qualified termination administrator shall not relieve any person from any obligation under part 1 of title I of ERISA.

PART 2550—RULES AND REGULATIONS FOR FIDUCIARY RESPONSIBILITY

■ 3. The authority citation for part 2550 is revised to read as follows:

Authority: 29 U.S.C. 1135, sec. 102, Reorganization Plan No. 4 of 1978, 5 U.S.C. App. at 727 (2012) and Secretary of Labor's Order No. 1–2011, 77 FR 1088 (Jan. 9, 2012). Section 2550.401c–1 also issued under 29 U.S.C. 1101. Sections 2550.404a–2 and 2550.404a–3 also issued under sec. 657, Pub. L. 107–16, 115 Stat. 38. Sections 2550.404a–5, 2550.404c–1 and 2550.404c–5 also issued under 29 U.S.C. 1104. Sec. 2550.408b–1 also issued under 29 U.S.C. 1108(b)(1). Sec. 2550.408b–19 also issued under sec. 611, Pub. L. 109–280, 120 Stat. 780, 972. Sec. 2550.412–1 also issued under 29 U.S.C. 1112.

■ 4. Revise § 2550.404a–3 to read as follows:

§ 2550.404a–3 Safe harbor for distributions from terminated individual account plans.

(a) *General.* (1) This section provides a safe harbor under which a fiduciary (including a qualified termination administrator, within the meaning of § 2578.1(g) or (j)(3) of this chapter) of a terminated individual account plan, as described in paragraph (a)(2) of this section, will be deemed to have satisfied its duties under section 404(a) of the Employee Retirement Income Security Act of 1974, as amended (the Act), 29 U.S.C. 1001 *et seq.,* in connection with a distribution described in paragraph (b) of this section.

(2) This section shall apply to an individual account plan only if—

(i) In the case of an individual account plan that is an abandoned plan within the meaning of § 2578.1 of this chapter, such plan was intended to be maintained as a tax-qualified retirement plan in accordance with the requirements of section 401(a) or 403(a), or as a tax deferred annuity plan in accordance with section 403(b) of the Internal Revenue Code of 1986 (Code); or

(ii) In the case of any other individual account plan, such plan is maintained in accordance with the requirements of section 401(a), 403(a), or 403(b) of the Code at the time of the distribution.

(3) The standards set forth in this section apply solely for purposes of determining whether a fiduciary meets the requirements of this safe harbor. Such standards are not intended to be the exclusive means by which a fiduciary might satisfy their responsibilities under the Act with respect to making distributions described in this section.

(b) *Distributions.* This section shall apply to a distribution from a terminated individual account plan if, in connection with such distribution:

(1) The participant or beneficiary, on whose behalf the distribution will be made, was furnished notice in accordance with paragraph (e) of this section or, in the case of an abandoned

plan, § 2578.1(d)(2)(vi) of this chapter, and

(2) The participant or beneficiary failed to elect a form of distribution within 30 days of the furnishing of the notice described in paragraph (b)(1) of this section.

(c) *Safe harbor.* A fiduciary that meets the conditions of paragraph (d) of this section shall, with respect to a distribution described in paragraph (b) of this section, be deemed to have satisfied its duties under section 404(a) of the Act with respect to the distribution of benefits, selection of a transferee entity described in paragraph (d)(1)(i) through (v) of this section, and the investment of funds in connection with the distribution.

(d) *Conditions.* A fiduciary shall qualify for the safe harbor described in paragraph (c) of this section if:

(1) The distribution described in paragraph (b) of this section is made to any of the following transferee entities—

(i) To an individual retirement plan within the meaning of section 7701(a)(37) of the Code;

(ii) In the case of a distribution on behalf of a designated beneficiary (as defined by section 401(a)(9)(E) of the Code) who is not the surviving spouse of the deceased participant, to an inherited individual retirement plan (within the meaning of section 402(c)(11) of the Code) established to receive the distribution on behalf of the nonspouse beneficiary;

(iii) In the case of a distribution by a qualified termination administrator (other than a bankruptcy trustee described in § 2578.1(j)(3) of this chapter or an eligible designee described in § 2578.1(j)(4)(ii) of this chapter) with respect to which the amount to be distributed is $1,000 or less and that amount is less than the minimum amount required to be invested in an individual retirement plan product offered by the qualified termination administrator to the public at the time of the distribution, to:

(A) An interest-bearing federally insured bank or savings association account in the name of the participant or beneficiary,

(B) The unclaimed property fund of the State in which the participant's or beneficiary's last known address is located, or

(C) An individual retirement plan (described in paragraph (d)(1)(i) or (d)(1)(ii) of this section) offered by a financial institution other than the qualified termination administrator to the public at the time of the distribution; or

(iv) In the case of a distribution by a bankruptcy trustee as described in § 2578.1(j)(3) of this chapter or an eligible designee as described in § 2578.1(j)(4)(ii) of this chapter with respect to which the amount to be distributed is $1,000 or less and such bankruptcy trustee or eligible designee, after reasonable and good faith efforts, is unable to locate an individual retirement plan provider who will accept the distribution, to either distribution option described in paragraph (d)(1)(iii)(A) or (B) of this section.

(v) Notwithstanding paragraphs (d)(1)(iii) and (iv) of this section—

(A) The qualified termination administrator may disregard the $1,000 threshold therein if the qualified termination administrator reasonably and in good faith finds that—

(*1*) The participant is deceased;

(*2*) The designated beneficiary or beneficiaries are deceased or unable to be identified based on records located and updated pursuant to § 2578.1(d)(2)(i) of this chapter;

(*3*) The estate of the participant is not the designated beneficiary; and

(*4*) The qualified termination administrator has no actual knowledge of any claims by any person to all or part of the deceased participant's account.

(B) If the estate of the participant is the designated beneficiary, the qualified termination administrator may disregard the $1,000 threshold therein if the qualified termination administrator reasonably and in good faith finds that—

(*1*) An estate does not exist or cannot be found;

(*2*) The qualified termination administrator has no actual knowledge of any claims by any person to all or part of the deceased participant's account; and

(*3*) The qualified termination administrator is unable to establish an individual retirement plan for the benefit of the estate of the participant.

(C) A summary of the pertinent findings made in paragraph (d)(1)(v)(A) or (B) of this section must be included in the notice described in § 2578.1(d)(2)(ix)(G) (the Final Notice) of this chapter, including the basis for the findings (including the name and last known address of the beneficiary, if known) and an attestation that the qualified termination administrator has the full name and last known address of the deceased participant.

(2) Except with respect to distributions to State unclaimed property funds (described in paragraph (d)(1)(iii)(B) of this section), the fiduciary enters into a written agreement with the transferee entity which provides:

(i) The distributed funds shall be invested in an investment product designed to preserve principal and provide a reasonable rate of return, whether or not such return is guaranteed, consistent with liquidity (except that distributions under paragraph (d)(1)(iii)(A) of this section to a bank or savings account are not required to be invested in such a product);

(ii) For purposes of paragraph (d)(2)(i) of this section, the investment product shall—

(A) Seek to maintain, over the term of the investment, the dollar value that is equal to the amount invested in the product by the individual retirement plan (described in paragraph (d)(1)(i) or (d)(1)(ii) of this section), and

(B) Be offered by a State or federally regulated financial institution, which shall be: a bank or savings association, the deposits of which are insured by the Federal Deposit Insurance Corporation; a credit union, the member accounts of which are insured within the meaning of section 101(7) of the Federal Credit Union Act; an insurance company, the products of which are protected by State guaranty associations; or an investment company registered under the Investment Company Act of 1940;

(iii) All fees and expenses attendant to the transferee plan (described in paragraph (d)(1)(i) or (d)(1)(ii) of this section) or account (described in paragraph (d)(1)(iii)(A) of this section), including investments of such plan, (*e.g.,* establishment charges, maintenance fees, investment expenses, termination costs and surrender charges), shall not exceed the fees and expenses charged by the provider of the plan or account for comparable plans or accounts established for reasons other than the receipt of a distribution under this section; and

(iv) The participant or beneficiary on whose behalf the fiduciary makes a distribution shall have the right to enforce the terms of the contractual agreement establishing the plan (described in paragraph (d)(1)(i) or (d)(1)(ii) of this section) or account (described in paragraph (d)(1)(iii)(A) of this section), with regard to their transferred account balance, against the plan or account provider.

(3) Both the fiduciary's selection of a transferee plan (described in paragraph (d)(1)(i) or (d)(1)(ii) of this section) or account (described in paragraph (d)(1)(iii)(A) of this section) and the investment of funds would not result in a prohibited transaction under section 406 of the Act, or if so prohibited such

actions are exempted from the prohibited transaction provisions by a prohibited transaction exemption issued pursuant to section 408(a) of the Act.

(e) *Notice to participants and beneficiaries.* (1) *Content.* Each participant or beneficiary of the plan shall be furnished a notice written in a manner calculated to be understood by the average plan participant and containing the following:

(i) The name of the plan;

(ii) A statement of the account balance, the date on which the amount was calculated, and, if relevant, an indication that the amount to be distributed may be more or less than the amount stated in the notice, depending on investment gains or losses and the administrative cost of terminating the plan and distributing benefits;

(iii) A description of the distribution options available under the plan and a request that the participant or beneficiary elect a form of distribution and inform the plan administrator (or other fiduciary) identified in paragraph (e)(1)(vii) of this section of that election;

(iv) A statement explaining that, if a participant or beneficiary fails to make an election within 30 days from receipt of the notice, the plan will distribute the account balance of the participant or beneficiary to an individual retirement plan (*i.e.,* individual retirement account or annuity described in paragraph (d)(1)(i) or (d)(1)(ii) of this section) and the account balance will be invested in an investment product designed to preserve principal and provide a reasonable rate of return and liquidity;

(v) A statement explaining what fees, if any, will be paid from the participant or beneficiary's individual retirement plan (described in paragraph (d)(1)(i) or (d)(1)(ii) of this section), if such information is known at the time of the furnishing of this notice;

(vi) The name, address and phone number of the individual retirement plan (described in paragraph (d)(1)(i) or (d)(1)(ii) of this section) provider, if such information is known at the time of the furnishing of this notice; and

(vii) The name, address, and telephone number of the plan administrator (or other fiduciary) from whom a participant or beneficiary may obtain additional information concerning the termination.

(2) *Manner of furnishing notice.* (i) For purposes of paragraph (e)(1) of this section, a notice shall be furnished to each participant or beneficiary in accordance with the requirements of § 2520.104b–1(b)(1) of this chapter to the last known address of the participant or beneficiary; and

(ii) In the case of a notice that is returned to the plan as undeliverable, the plan fiduciary shall, consistent with its duties under section 404(a)(1) of the Act, take steps to locate the participant or beneficiary and provide notice prior to making the distribution. If, after such steps, the fiduciary is unsuccessful in locating and furnishing notice to a participant or beneficiary, the participant or beneficiary shall be deemed to have been furnished the notice and to have failed to make an election within 30 days for purposes of paragraph (b)(2) of this section.

(f) *Model notice.* The appendix to this part contains a model notice that may be used to discharge the notification requirements under this section for plans other than abandoned plans. Use of the model notice is not mandatory. However, use of an appropriately completed model notice will be deemed to satisfy the requirements of paragraph (e)(1) of this section. For a model notice for abandoned plans, see Appendix D to part 2578.

■ 5. Add Appendix A to part 2550 to read as follows:

Appendix A to Part 2550—Model Notice for Section 404a–3

NOTICE OF PLAN TERMINATION

[DO NOT USE FOR ABANDONED PLANS]

[*Date of notice*]

[*Name and last known address of plan participant or beneficiary*]

Re: [*Name of plan*]

Dear [*Name of plan participant or beneficiary*]:

This notice is to inform you that [*name of the plan*] (the Plan) has been terminated.

We have determined that you have an interest in the Plan, either as a plan participant or beneficiary. Your account balance in the Plan on [*date*] is/was [*account balance*]. We will be distributing this money as permitted under the terms of the Plan and federal regulations. {*If applicable, insert the following sentence:* The actual amount of your distribution may be more or less than the amount stated in this notice depending on investment gains or losses and the administrative cost of terminating your plan and distributing your benefits.}

Your distribution options under the Plan are {*add a description of the Plan's distribution options*}. It is very important that you elect one of these forms of distribution and inform us of your election. The process for informing us of this election is {*enter a description of the Plan's election process*}.

If you do not make an election within 30 days from your receipt of this notice, your account balance will be transferred directly to an individual retirement plan (inherited individual retirement plan in the case of a nonspouse beneficiary). {*If the name of the provider of the individual retirement plan is known, include the following sentence:* The name of the provider of the individual retirement plan is [*name, address and phone number of the individual retirement plan provider*].} Pursuant to federal law, your money in the individual retirement plan would then be invested in an investment product designed to preserve principal and provide a reasonable rate of return and liquidity. {*If fee information is known, include the following sentence:* Should your money be transferred to the individual retirement plan described, above, [*name of the financial institution*] will charge your account the following fees for its services: {*add a statement of fees, if any, that will be paid from the participant or beneficiary's individual retirement plan*}.}

For more information about the termination, your account balance, or distribution options, please contact [*name, address, and telephone number of the plan administrator or other appropriate contact person*].

Sincerely,

[*Name of plan administrator or appropriate designee*]

[*Name of plan*]

PART 2578—RULES AND REGULATIONS FOR ABANDONED PLANS

■ 6. The authority citation for part 2578 continues to read as follows:

Authority: 29 U.S.C. 1135; 1104(a); 1103(d)(1).

■ 7. Revise § 2578.1 to read as follows:

§ 2578.1 Termination of abandoned individual account plans.

(a) *General.* The purpose of this part is to establish standards for the termination and winding up of an individual account plan (as defined in section 3(34) of the Employee Retirement Income Security Act of 1974 (ERISA or the Act)) with respect to the situations described in (a)(1) or (2) of this section.

(1) A qualified termination administrator has determined there is no responsible plan sponsor or plan administrator within the meaning of section 3(16)(B) and (A) of the Act, respectively, to perform such acts.

(2) An order for relief under chapter 7 of title 11 of the United States Code (the United States Bankruptcy Code) has been entered with respect to the plan sponsor.

(b) *Finding of abandonment.* (1) A qualified termination administrator (as defined in paragraph (g) of this section) may find an individual account plan to be abandoned when:

(i) Either: (A) No contributions to, or distributions from, the plan have been made for a period of at least 12 consecutive months immediately preceding the date on which the determination is being made; or

(B) Other facts and circumstances (such as communications from

participants and beneficiaries regarding distributions) known to the qualified termination administrator suggest that the plan is or may become abandoned by the plan sponsor; and

(ii) Following reasonable efforts to locate or communicate with the plan sponsor, the qualified termination administrator determines that the plan sponsor:

(A) No longer exists;

(B) Cannot be located; or

(C) Is unable to maintain the plan.

(2) Notwithstanding paragraph (b)(1) of this section, a qualified termination administrator may not find a plan to be abandoned if, at any time before the plan is deemed terminated pursuant to paragraph (c) of this section, the qualified termination administrator receives an objection from the plan sponsor regarding the finding of abandonment and proposed termination.

(3) A qualified termination administrator shall, for purposes of paragraph (b)(1)(ii) of this section, be deemed to have made a reasonable effort to locate or communicate with the plan sponsor if the qualified termination administrator sends to the last known address of the plan sponsor, and, in the case of a plan sponsor that is a corporation, to the address of the person designated as the corporation's agent for service of legal process, by a method of delivery requiring acknowledgement of receipt, the notice described in paragraph (b)(5) of this section.

(4) If receipt of the notice described in paragraph (b)(5) of this section is not acknowledged pursuant to paragraph (b)(3) of this section, the qualified termination administrator shall be deemed to have made a reasonable effort to locate or communicate with the plan sponsor if the qualified termination administrator contacts known service providers (other than itself) of the plan and requests the current address of the plan sponsor from such service providers and, if such information is provided, the qualified termination administrator sends to each such address, by a method of delivery requiring acknowledgement of receipt, the notice described in paragraph (b)(5) of this section.

(5) The notice referred to in paragraph (b)(3) of this section shall contain the following information:

(i) The name and address of the qualified termination administrator;

(ii) The name of the plan;

(iii) The account number or other identifying information relating to the plan;

(iv) A statement that the plan may be terminated and benefits distributed pursuant to 29 CFR 2578.1 if the plan sponsor fails to contact the qualified termination administrator within 30 days;

(v) The name, address, and telephone number of the person, office, or department that the plan sponsor must contact regarding the plan;

(vi) A statement that if the plan is terminated pursuant to 29 CFR 2578.1, notice of such termination will be furnished to the U.S. Department of Labor's Employee Benefits Security Administration;

(vii) The following statement: ''The U.S. Department of Labor requires that you be informed that, as a fiduciary or plan administrator or both, you may be personally liable for costs, civil penalties, excise taxes, etc. as a result of your acts or omissions with respect to this plan. The termination of this plan will not relieve you of your liability for any such costs, penalties, taxes, etc.''; and

(viii) A statement that the plan sponsor may contact the U.S. Department of Labor for more information about the federal law governing the termination and winding-up process for abandoned plans and the telephone number of the appropriate Employee Benefits Security Administration contact person.

(c) *Deemed termination.* (1) Except as provided in paragraph (c)(2) of this section, if a qualified termination administrator finds (pursuant to paragraph (b)(1) of this section) that an individual account plan has been abandoned, or if a plan is considered abandoned due to the entry of an order for relief under chapter 7 of the United States Bankruptcy Code (pursuant to paragraph (j)(2) of this section), the plan shall be deemed to be terminated on the ninetieth (90th) day following the date of the letter from the Employee Benefits Security Administration acknowledging receipt of the notice described in paragraph (c)(3) or (j)(6) of this section.

(2) If, prior to the end of the 90-day period described in paragraph (c)(1) of this section, the Department notifies the qualified termination administrator that it—

(i) Objects to the termination of the plan, the plan shall not be deemed terminated under paragraph (c)(1) of this section until the qualified termination administrator is notified that the Department has withdrawn its objection; or

(ii) Waives the 90-day period described in paragraph (c)(1), the plan shall be deemed terminated upon the qualified termination administrator's receipt of such notification.

(3) Following a qualified termination administrator's finding, pursuant to paragraph (b)(1) of this section, that an individual account plan has been abandoned, the qualified termination administrator shall furnish to the U.S. Department of Labor in accordance with instructions published by the Department in the Abandoned Plans section of the Employee Benefits Security Administration's website a notice of plan abandonment and intent to serve as qualified termination administrator that is signed and dated by the qualified termination administrator and that includes the following information:

(i) *Qualified termination administrator information.* (A) The name, EIN, address, and telephone number of the person electing to be the qualified termination administrator, including the address, email address, and telephone number of the person signing the notice (or other contact person, if different from the person signing the notice);

(B) A statement that the person (identified in paragraph (c)(3)(i)(A) of this section) is a qualified termination administrator within the meaning of paragraph (g) of this section and elects to terminate and wind up the plan (identified in paragraph (c)(3)(ii)(A) of this section) in accordance with the provisions of this section;

(ii) *Plan information.* (A) The name, address, telephone number, account number, EIN of the plan sponsor (if known), and plan number used on the Form 5500 Annual Return/Report filed for the plan with respect to which the person is electing to serve as the qualified termination administrator;

(B) The name and last known address and telephone number of the plan sponsor; and

(C) The estimated number of participants and beneficiaries with accounts in the plan;

(iii) *Findings.* A statement that the person electing to be the qualified termination administrator finds that the plan (identified in paragraph (c)(3)(ii)(A) of this section) is abandoned pursuant to paragraph (b) of this section. This statement shall include an explanation of the basis for such a finding, specifically referring to the provisions in paragraph (b)(1) of this section, a description of the specific steps (set forth in paragraphs (b)(3) and (b)(4) of this section) taken to locate or communicate with the known plan sponsor, and a statement that no objection has been received from the plan sponsor;

(iv) *Plan asset information.* (A) The estimated value of the plan's assets held

by the person electing to be the qualified termination administrator;

(B) The length of time plan assets have been held by the person electing to be the qualified termination administrator, if such period of time is less than 12 months;

(C) An identification of any assets with respect to which there is no readily ascertainable fair market value, as well as information, if any, concerning the value of such assets; and

(D) An identification of delinquent contributions described in paragraph (d)(2)(iii) of this section;

(v) *Service provider information.* (A) The name, address, and telephone number of known service providers (*e.g.,* record keeper, accountant, lawyer, other asset custodian(s)) to the plan; and

(B) An identification of any services considered necessary to carry out the qualified termination administrator's authority and responsibility under this section, the name of the service provider(s) that is expected to provide such services, and an itemized estimate of expenses attendant thereto expected to be paid out of plan assets by the qualified termination administrator; and

(vi) *Perjury statement.* A statement that the information being provided in the notice is true and complete based on the knowledge of the person electing to be the qualified termination administrator, and that the information is being provided by the qualified termination administrator under penalty of perjury.

(d) *Winding up the affairs of the plan.* (1) In any case where an individual account plan is deemed to be terminated pursuant to paragraph (c) of this section, the qualified termination administrator shall take steps as may be necessary or appropriate to wind up the affairs of the plan and distribute benefits to the plan's participants and beneficiaries.

(2) For purposes of paragraph (d)(1) of this section, except as provided pursuant to paragraph (j)(7) of this section (relating to Chapter 7 ERISA Plans), the qualified termination administrator shall:

(i) *Update plan records.* (A) Undertake reasonable and diligent efforts to locate and update plan records necessary to determine the benefits payable under the terms of the plan to each participant and beneficiary.

(B) For purposes of paragraph (d)(2)(i)(A) of this section, a qualified termination administrator shall not have failed to make reasonable and diligent efforts to update plan records because the administrator determines in good faith that updating the records is either impossible or involves significant cost to the plan in relation to the total assets of the plan.

(ii) *Calculate benefits.* Use reasonable care in calculating the benefits payable to each participant or beneficiary based on plan records described in paragraph (d)(2)(i) of this section. A qualified termination administrator shall not have failed to use reasonable care in calculating benefits payable solely because the qualified termination administrator—

(A) Treats as forfeited an account balance that, taking into account estimated forfeitures and other assets allocable to the account, is less than the estimated share of plan expenses allocable to that account, and reallocates that account balance to defray plan expenses or to other plan accounts in accordance with paragraph (d)(2)(ii)(B) of this section;

(B) Allocates expenses and unallocated assets in accordance with the plan document, or, if the plan document is not available, is ambiguous, or if compliance with the plan is unfeasible,

(*1*) Allocates unallocated assets (including forfeitures and assets in a suspense account) to participant accounts on a per capita basis (allocated equally to all accounts); and

(*2*) Allocates expenses on a pro rata basis (proportionately in the ratio that each individual account balance bears to the total of all individual account balances) or on a per capita basis (allocated equally to all accounts).

(iii) *Report delinquent contributions.* (A) Notify the Department of any known contributions (either employer or employee) owed to the plan in conjunction with the filing of the notification required in paragraphs (c)(3) or (d)(2)(ix) of this section.

(B) Except as provided in paragraph (j)(7)(i) of this section, nothing in paragraph (d)(2)(iii)(A) of this section or any other provision of the Act shall be construed to impose an obligation on the qualified termination administrator to collect delinquent contributions on behalf of the plan, provided that the qualified termination administrator satisfies the requirements of paragraph (d)(2)(iii)(A) of this section.

(iv) *Engage service providers.* Engage, on behalf of the plan, such service providers as are necessary for the qualified termination administrator to wind up the affairs of the plan and distribute benefits to the plan's participants and beneficiaries in accordance with paragraph (d)(1) of this section.

(v) *Pay reasonable expenses.* (A) Pay, from plan assets, the reasonable expenses of carrying out the qualified termination administrator's authority and responsibility under this section.

(B) Expenses of plan administration shall be considered reasonable solely for purposes of paragraph (d)(2)(v)(A) of this section if:

(*1*) Such expenses are for services necessary to wind up the affairs of the plan and distribute benefits to the plan's participants and beneficiaries,

(*2*) Such expenses: (*i*) Are consistent with industry rates for such or similar services, based on the experience of the qualified termination administrator; and

(*ii*) Are not in excess of rates ordinarily charged by the qualified termination administrator (or affiliate) for the same or similar services provided to customers that are not plans terminated pursuant to this section, if the qualified termination administrator (or affiliate) provides the same or similar services to such other customers, and

(*3*) The payment of such expenses would not constitute a prohibited transaction under the Act or is exempted from such prohibited transaction provisions pursuant to section 408(a) of the Act.

(vi) *Notify participants.* (A) Furnish to each participant or beneficiary of the plan a notice written in a manner calculated to be understood by the average plan participant and containing the following:

(*1*) The name of the plan;

(*2*) A statement that the plan has been determined to be abandoned by the plan sponsor, or in the case of a Chapter 7 ERISA Plan (described in paragraph (j)(2) of this section) a statement that the plan sponsor is in liquidation under chapter 7 of the United States Bankruptcy Code, and, therefore, has been terminated pursuant to regulations issued by the U.S. Department of Labor;

(*3*)(*i*) A statement of the participant's or beneficiary's account balance and the date on which it was calculated by the qualified termination administrator, and

(*ii*) The following statement: ''The actual amount of your distribution may be more or less than the amount stated in this letter depending on investment gains or losses and the administrative cost of terminating your plan and distributing your benefits.'';

(*4*) A description of the distribution options available under the plan and a request that the participant or beneficiary elect a form of distribution and inform the qualified termination administrator (or designee) of that election;

(*5*) A statement explaining that, if a participant or beneficiary fails to make an election within 30 days from receipt of the notice, the qualified termination

administrator will distribute the account balance of the participant or beneficiary directly:

(*i*) To an individual retirement plan (*i.e.,* individual retirement account or annuity),

(*ii*) To an inherited individual retirement plan described in § 2550.404a–3(d)(1)(ii) of this chapter (in the case of a distribution on behalf of a distributee other than a participant or spouse),

(*iii*) In any case where the amount to be distributed meets the conditions in § 2550.404a–3(d)(1)(iii) or (iv) of this chapter, to an interest-bearing federally insured bank account, the unclaimed property fund of the State of the last known address of the participant or beneficiary, or an individual retirement plan (described in § 2550.404a–3(d)(1)(i) or (d)(1)(ii) of this chapter) or

(*iv*) To an annuity provider in any case where the qualified termination administrator determines that the survivor annuity requirements in sections 401(a)(11) and 417 of the Internal Revenue Code (or section 205 of ERISA) prevent a distribution under paragraph (d)(2)(vii)(B)(*1*) of this section;

(*6*) In the case of a distribution to an individual retirement plan (described in § 2550.404a–3(d)(1)(i) or (d)(1)(ii) of this chapter) a statement explaining that the account balance will be invested in an investment product designed to preserve principal and provide a reasonable rate of return and liquidity;

(*7*) A statement of the fees, if any, that will be paid from the participant's or beneficiary's individual retirement plan (described in § 2550.404a–3(d)(1)(i) or (d)(1)(ii) of this chapter) or other account (described in § 2550.404a–3(d)(1)(iii)(A) of this chapter), if such information is known at the time of the furnishing of this notice;

(*8*) The name, address and phone number of the provider of the individual retirement plan (described in § 2550.404a–3(d)(1)(i) or (d)(1)(ii) of this chapter), qualified survivor annuity, or other account (described in § 2550.404a–3(d)(1)(iii)(A) of this chapter), if such information is known at the time of the furnishing of this notice; and

(*9*) The name, address, and telephone number of the qualified termination administrator and, if different, the name, address and phone number of a contact person (or entity) for additional information concerning the termination and distribution of benefits under this section.

(B)(*1*) For purposes of paragraph (d)(2)(vi)(A) of this section, a notice shall be furnished to each participant or beneficiary in accordance with the requirements of § 2520.104b–1(b)(1) of this chapter to the last known address of the participant or beneficiary; and

(*2*) In the case of a notice that is returned to the qualified termination administrator as undeliverable, the qualified termination administrator shall, consistent with the duties of a fiduciary under section 404(a)(1) of the Act, take steps to locate and provide notice to the participant or beneficiary prior to making a distribution pursuant to paragraph (d)(2)(vii) of this section. If, after such steps, the qualified termination administrator is unsuccessful in locating and furnishing notice to a participant or beneficiary, the participant or beneficiary shall be deemed to have been furnished the notice and to have failed to make an election within the 30-day period described in paragraph (d)(2)(vii) of this section.

(vii) *Distribute benefits.* (A) Distribute benefits in accordance with the form of distribution elected by each participant or beneficiary with spousal consent, if required.

(B) If the participant or beneficiary fails to make an election within 30 days from the date the notice described in paragraph (d)(2)(vi) of this section is furnished, distribute benefits—

(*1*) In accordance with § 2550.404a–3 of this chapter; or

(*2*) If a qualified termination administrator determines that the survivor annuity requirements in sections 401(a)(11) and 417 of the Internal Revenue Code (or section 205 of ERISA) prevent a distribution under paragraph (d)(2)(vii)(B)(*1*) of this section, in any manner reasonably determined to achieve compliance with those requirements.

(C) For purposes of distributions pursuant to paragraph (d)(2)(vii)(B) of this section, the qualified termination administrator may designate itself (or an affiliate) as the transferee of such proceeds, and invest such proceeds in a product in which it (or an affiliate) has an interest, only if such designation and investment is exempted from the prohibited transaction provisions under the Act pursuant to section 408(a) of the Act.

(viii) *Special Terminal Report for Abandoned Plans.* File the Special Terminal Report for Abandoned Plans in accordance with § 2520.103–13 of this chapter.

(ix) *Final Notice.* No later than two months after the end of the month in which the qualified termination administrator satisfies the requirements in paragraph (d)(2)(i) through (vii) of this section, furnish to the U.S. Department of Labor in accordance with instructions published by the Department in the Abandoned Plans section of the Employee Benefits Security Administration's website, a notice, signed and dated by the qualified termination administrator, containing the following information:

(A) The name, EIN, address, email address, and telephone number of the qualified termination administrator, including the address, email address, and telephone number of the person signing the notice (or other contact person, if different from the person signing the notice), and if applicable with respect to a Chapter 7 ERISA Plan (as described in paragraph (j)(2) of this section), the name, address (including email address), and telephone number of the bankruptcy trustee if the bankruptcy trustee is not the qualified termination administrator;

(B) The name, account number, EIN, and plan number used on the Form 5500 Annual Return/Report filed for the plan with respect to which the person served as the qualified termination administrator;

(C) A statement that the plan has been terminated and all the plan's assets have been distributed to the plan's participants and beneficiaries on the basis of the best available information;

(D) A statement that plan expenses were paid out of plan assets by the qualified termination administrator in accordance with the requirements of paragraph (d)(2)(v) or (j)(7)(iv) of this section;

(E) If fees and expenses paid by the plan exceed by 20 percent or more the estimate required by paragraph (c)(3)(v)(B) or (j)(6)(vi)(B) of this section, a statement that actual fees and expenses exceeded estimated fees and expenses and the reasons for such additional costs;

(F) An identification of delinquent contributions described in paragraph (d)(2)(iii) of this section, or if applicable with respect to a Chapter 7 ERISA Plan (as described in paragraph (j)(2) of this section), an identification of delinquent contributions and evidence of other fiduciary breaches described in paragraph (j)(7)(ii) of this section (if not already reported under paragraphs (c)(3) or (j)(6) of this section);

(G) For each distribution in accordance with § 2550.404a–3(d)(1)(v) of this chapter (relating to distributions on behalf of deceased participants and beneficiaries), a summary of the pertinent findings as required by § 2550.404a–3(d)(1)(v)(*C*) of this chapter; and

(H) A statement that the information being provided in the notice is true and

complete based on the knowledge of the qualified termination administrator, and that the information is being provided by the qualified termination administrator under penalty of perjury.

(3) The terms of the plan shall, for purposes of title I of ERISA, be deemed amended to the extent necessary to allow the qualified termination administrator to wind up the plan in accordance with this section.

(e) *Limited liability.* (1)(i) Except as otherwise provided in paragraph (e)(1)(ii) and (iii) of this section, to the extent that the activities enumerated in paragraphs (d)(2) and (j)(7) of this section involve the exercise of discretionary authority or control that would make the qualified termination administrator a fiduciary within the meaning of section 3(21) of the Act, the qualified termination administrator shall be deemed to satisfy its responsibilities under section 404(a) of the Act with respect to such activities, provided that the qualified termination administrator complies with the requirements of paragraph (d)(2) and (j)(7) of this section as applicable.

(ii) A qualified termination administrator shall be responsible for the selection and monitoring of any service provider (other than monitoring a provider selected pursuant to paragraph (d)(2)(vii)(B) of this section) determined by the qualified termination administrator to be necessary to the winding up of the affairs of the plan, as well as ensuring the reasonableness of the compensation paid for such services. If a qualified termination administrator selects and monitors a service provider in accordance with the requirements of section 404(a)(1) of the Act, the qualified termination administrator shall not be liable for the acts or omissions of the service provider with respect to which the qualified termination administrator does not have knowledge.

(iii) For purposes of a distribution pursuant to paragraph (d)(2)(vii)(B)(*2*) of this section, a qualified termination administrator shall be responsible for the selection of an annuity provider in accordance with section 404 of the Act.

(2) Nothing herein shall be construed to impose an obligation on the qualified termination administrator to conduct an inquiry or review to determine whether or what breaches of fiduciary responsibility may have occurred with respect to a plan prior to becoming the qualified termination administrator for such plan.

(3) If assets of an abandoned plan are held by a person other than the qualified termination administrator, such person shall not be treated as in violation of section 404(a) of the Act solely on the basis that the person cooperated with and followed the directions of the qualified termination administrator in carrying out its responsibilities under this section with respect to such plan, provided that, in advance of any transfer or disposition of any assets at the direction of the qualified termination administrator, such person confirms with the Department of Labor that the person representing to be the qualified termination administrator with respect to the plan is the qualified termination administrator recognized by the Department of Labor.

(4) If the qualified termination administrator is an eligible designee described in § 2578.1(j)(4) of this chapter, designated by a bankruptcy trustee described in § 2578.1(j)(3) of this chapter, both the bankruptcy trustee and the eligible designee shall be treated as the qualified termination administrator for purposes of paragraphs (e)(1)(i), (e)(2) and (f) of this section. Nothing in this paragraph (e)(4) shall serve to relieve the bankruptcy trustee from its obligations under or limit its liability for a failure to comply with paragraph (j)(5).

(f) *Continued liability.* Nothing in this section shall serve to relieve or limit the liability of any person other than the qualified termination administrator due to a violation of ERISA.

(g) *Qualified termination administrator.* A termination administrator is qualified under this section only if:

(1) It is eligible to serve as a trustee or issuer of an individual retirement plan, within the meaning of section 7701(a)(37) of the Internal Revenue Code, and

(2) It holds assets of the plan that is found abandoned pursuant to paragraph (b) of this section.

(h) *Affiliate.* (1) The term affiliate means any person directly or indirectly controlling, controlled by, or under common control with, the person; or any officer, director, partner or employee of the person.

(2) For purposes of paragraph (h)(1) of this section, the term control means the power to exercise a controlling influence over the management or policies of a person other than an individual.

(i) *Model notices.* Appendices to this part contain model notices that are intended to assist qualified termination administrators in discharging the notification requirements under this section. Their use is not mandatory. However, the use of appropriately completed model notices will be deemed to satisfy the requirements of paragraphs (b)(5), (c)(3), (d)(2)(vi), (d)(2)(ix), and (j)(6) of this section.

(j) *Special rules for Chapter 7 ERISA Plans.* (1) *In general.* This paragraph (j) contains special rules for individual account plans of sponsors in liquidation under chapter 7 of the United States Bankruptcy Code (Chapter 7 ERISA Plans). These special rules modify, augment, or supersede otherwise applicable provisions in paragraphs (a) through (i) of this section.

(2) *Deemed abandonment.* If the sponsor of an individual account plan is in liquidation under chapter 7 of the United States Bankruptcy Code, the requirements of paragraph (b) do not apply, and the Chapter 7 ERISA Plan shall be considered abandoned upon the entry of an order for relief, except that the plan shall cease to be considered abandoned if at any time before the plan is deemed terminated pursuant to paragraph (c) of this section, the plan sponsor's chapter 7 liquidation proceeding is dismissed or converted to a proceeding under a different chapter of the United States Bankruptcy Code.

(3) *Qualified termination administrator.* For a plan deemed abandoned under paragraph (j)(2) of this section, the definition of ''qualified termination administrator'' in paragraph (g) of this section does not apply and only the bankruptcy trustee in the case, or an eligible designee (as defined in paragraph (j)(4) of this section), may be the qualified termination administrator.

(4) *Eligible designee.* The term ''eligible designee'' means—

(i) any person or entity who accepts in writing a designation by the bankruptcy trustee and who meets the requirements in paragraph (g) of this section; or

(ii) an '' independent bankruptcy trustee practitioner.'' An independent bankruptcy trustee practitioner is a person other than the bankruptcy trustee of the plan sponsor's case, who has served within the previous five years as a bankruptcy trustee in a case under chapter 7 of the Bankruptcy Code, who accepts in writing a designation by the bankruptcy trustee and who acknowledges in writing to the bankruptcy trustee that they are a fiduciary with respect to the plan.

(5) *Rules and conditions with respect to designating an eligible designee.*

(i) The term ''de minimis'' in paragraph (j)(7)(i) of this section means:

(A) Any amount that is equal to or less than $2,000; or

(B) Any amount greater than $2,000 if the property from which to collect delinquent contributions is a realizable value that is equal to or less than $2,000

net of all enforceable liens and applicable exemptions.

(ii) Prior to designating an eligible designee, a bankruptcy trustee must make reasonable and diligent efforts to determine whether the plan is owed any contributions (employer and employee) and the amount thereof. If the amount of contributions owed to the plan is more than a de minimis amount (as defined under paragraph (j)(5) of this section), the bankruptcy trustee shall designate an eligible designee (as defined in paragraph (j)(4) of this section) to be the qualified termination administrator for all purposes under this section.

(iii) The bankruptcy trustee shall at the time of the designation notify the eligible designee of its findings on the amount of delinquent contributions (employer and employee).

(iv) The bankruptcy trustee shall provide an eligible designee with reasonable access to any records under the control of the bankruptcy trustee that the eligible designee reasonably determines are necessary to enable the eligible designee to carry out its responsibilities under paragraph (j)(7) of this section.

(v) The bankruptcy trustee shall be responsible for the selection and monitoring of the eligible designee in accordance with section 404(a)(1)(A) and (B) of the Act.

(6) *Notice of intent to serve as qualified termination administrator.* In lieu of the content requirements in paragraph (c)(3) of this section, the qualified termination administrator shall furnish to the U.S. Department of Labor a notice of intent to serve as qualified termination administrator that is signed and dated by the qualified termination administrator and that includes the following information:

(i) *Qualified termination administrator information.* The name, address (including email address), and telephone number of the bankruptcy trustee and, if applicable, the name, EIN, address (including email address), and telephone number of any eligible designee acting as the qualified termination administrator;

(ii) *Plan information.* (A) The name, address, telephone number, account number, EIN of the plan sponsor (if known), and plan number used on the Form 5500 Annual Return/Report filed for the plan with respect to which the person is serving as the qualified termination administrator,

(B) The name and last known address and telephone number of the plan sponsor, and

(C) The estimated number of participants and beneficiaries with accounts in the plan;

(iii) *Chapter 7 information.* A statement that, pursuant to paragraph (j)(2) of this section, the plan is considered to be abandoned due to an entry of an order for relief under chapter 7 of the U.S. Bankruptcy Code, and a copy of the order or document entered in the case reflecting the bankruptcy trustee's appointment or authority to administer the plan sponsor's case;

(iv) *Fiduciary breaches.* Any information the qualified termination administrator believes may be evidence of other fiduciary breaches described in paragraph (j)(7)(ii) of this section.

(v) *Plan asset information.* (A) The estimated value of the plan's assets as of the date of the entry of an order for relief,

(B) The name, EIN, address (including email address) and telephone number of the entity that is holding these assets, and the length of time plan assets have been held by such entity, if the period of time is less than 12 months,

(C) An identification of any assets with respect to which there is no readily ascertainable fair market value, as well as information, if any, concerning the value of such assets, and

(D) An identification of delinquent contributions described in paragraph (j)(7)(i) of this section;

(vi) *Service provider information.* (A) The name, address, and telephone number of known service providers (*e.g.,* record keeper, accountant, lawyer, other asset custodian(s)) to the plan, and

(B) An identification of any services considered necessary to carry out the qualified termination administrator's authority and responsibility under this section, the name of the service provider(s) that is expected to provide such services, and an itemized estimate of expenses attendant thereto expected to be paid out of plan assets by the qualified termination administrator; and

(vii) *Perjury statement.* A statement that the information being provided in the notice is true and complete based on the knowledge of the person electing to be the qualified termination administrator, and that the information is being provided by the qualified termination administrator under penalty of perjury.

(7) *Winding up the affairs of the plan.* The qualified termination administrator shall comply with paragraph (d) of this section except as follows:

(i) *Delinquent contributions.* Except for qualified termination administrators of plans that are owed no more than a de minimis amount of contributions (employer and employee), the qualified termination administrator of a plan described in paragraph (j)(2) of this section shall, consistent with the duties of a fiduciary under section 404(a)(1) of the Act, take reasonable steps to collect delinquent contributions on behalf of the plan, taking into account the value of the plan assets involved, the likelihood of a successful recovery, and the expenses expected to be incurred in connection with collection.

(ii) *Report fiduciary breaches.* The qualified termination administrator must report delinquent contributions (employer and employee) owed to the plan, and any activity that the qualified termination administrator believes may be evidence of other fiduciary breaches that involve plan assets by a prior plan fiduciary. This information must be reported to the Employee Benefits Security Administration in conjunction with the filing of the notification required in paragraph (j)(6) (notice of intent to serve as qualified termination administrator) or (d)(2)(ix) (final notice) of this section. If, after the eligible designee completes the winding up of the plan, the bankruptcy trustee, in administering the debtor's estate, discovers additional information not already reported in the notification required in paragraphs (j)(6) or (d)(2)(ix) of this section that it believes may be evidence of fiduciary breaches that involve plan assets by a prior plan fiduciary, the bankruptcy trustee shall report such activity to the Employee Benefits Security Administration in a time and manner specified in instructions developed by the Office of Enforcement, Employee Benefits Security Administration, U.S. Department of Labor.

(iii) *Distributions.* Paragraph (d)(2)(vii)(C) of this section (relating to the ability of a qualified termination administrator to designate itself as the transferee of distribution proceeds in accordance with § 2550.404a–3) is not applicable in the case of a qualified termination administrator that is the bankruptcy trustee or an eligible designee defined under paragraph (j)(4)(ii) of this section.

(iv) *Pay reasonable expenses.* (A) If the qualified termination administrator is the bankruptcy trustee in the case, or an eligible designee as defined in paragraph (j)(4)(ii) of this section, then in lieu of the requirements in paragraph (d)(2)(v)(B)(*2*) of this section, such expenses are consistent with industry rates for such or similar services ordinarily charged by qualified termination administrators defined in paragraph (g) of this section.

(B) Notwithstanding paragraph (j)(7)(iv)(A) of this section, in lieu of the

requirements in paragraph (d)(2)(v)(B)(*2*) of this section, expenses incurred to comply with paragraph (j)(7)(i) of this section (pertaining to collecting delinquent contributions) are consistent with industry rates for such or similar services ordinarily approved by bankruptcy courts for persons representing or assisting a bankruptcy trustee in performing collection duties in chapter 7 matters.

(8) *Rule of accountability.* The bankruptcy trustee or eligible designee shall not, for themselves or the other, through waiver or otherwise, seek a release from liability under ERISA, or assert a defense of derived judicial immunity (or similar defense) in any action brought against the bankruptcy trustee or eligible designee arising out of its conduct under this regulation.

■ 8. Add Appendices A through E to part 2578 to read as follows:

Appendix A to Part 2578—Model Notice of Intent To Terminate Abandoned Plan

NOTICE OF INTENT TO TERMINATE PLAN

[*Date of notice*]

[*Name of plan sponsor*]
[*Last known address of plan sponsor*]

Re: [*Name of plan and account number or other identifying information*]

Dear [*Name of plan sponsor*]:

This letter is a notice of intent to terminate the above referenced plan and distribute benefits in accordance with the U.S. Department of Labor's Abandoned Plan Program. We will initiate the termination process under the Abandoned Plan Program unless you contact us within 30 days of your receipt of this notice. See 29 CFR 2578.1.

Our basis for taking this action is that our records reflect that there have been no contributions to, or distributions from, the plan within the past 12 months. {*If the basis for sending this notice is under 29 CFR 2578.1(b)(1)(i)(B), complete and include the sentence below rather than the sentence above.*} Our basis for taking this action is {*provide a description of the facts and circumstances indicating plan abandonment*}.

We are sending this notice to you because our records show that you are the sponsor of the subject plan. The U.S. Department of Labor requires that you be informed that, as a fiduciary or plan administrator or both, you may be personally liable for all costs, civil penalties, excise taxes, etc. as a result of your acts or omissions with respect to this plan. The termination of this plan by us will not relieve you of your liability for any such costs, penalties, taxes, etc. Federal law also requires us to notify the U.S. Department of Labor, Employee Benefits Security Administration, of the termination. For information about the federal law governing the termination of abandoned plans, you may contact the U.S. Department of Labor at 1.866.444.EBSA (3272) or *https://www.dol.gov/agencies/ebsa/about-ebsa/ask-a-question/ask-ebsa.*

Please contact [*name, address, and telephone number of the person, office, or department that the sponsor must contact regarding the plan*] within 30 days in order to prevent this action.

Sincerely,

[*Name and address of qualified termination administrator or appropriate designee*]

Appendix B to Part 2578—Model Notice of Plan Abandonment and Intent To Serve as Qualified Termination Administrator (for Plans Found Abandoned Pursuant to 29 CFR 2578.1(b))

BILLING CODE 4510–29–P

NOTIFICATION OF PLAN ABANDONMENT AND INTENT TO SERVE AS QUALIFIED TERMINATION ADMINISTRATOR

[*Date of notice*]

Abandoned Plan Coordinator, Office of Enforcement
Employee Benefits Security Administration
U.S. Department of Labor
200 Constitution Ave., NW, Suite 600
Washington, DC, 20210

Re:	Plan Identification	Qualified Termination Administrator
	[Plan name, EIN and plan number from Plan's Form 5500	[N*ame*]
	[Plan account number]	[*Address*]
	[Address]	[*E-mail address*]
	[Telephone number]	[*Telephone number*]
		[*EIN*]

Abandoned Plan Coordinator:

Pursuant to 29 CFR 2578.1(b), we have determined that the subject plan is or may become abandoned by its sponsor. We are eligible to serve as a Qualified Termination Administrator for purposes of terminating and winding up the plan in accordance with 29 CFR 2578.1, and hereby elect to do so.

We find that {*check the appropriate box below and provide additional information as necessary*}:

□ There have been no contributions to, or distributions from, the plan for a period of at least 12 consecutive months immediately preceding the date of this letter. Our records indicate that the date of the last contribution or distribution was {*enter appropriate date*}.

□ The following facts and circumstances suggest that the plan is or may become abandoned by the plan sponsor {*add description below*}:

_____

_____

_____

We have also determined that the plan sponsor {*check appropriate box below*}:

□ No longer exists

□ Cannot be located

□ Is unable to maintain the plan

We have taken the following steps to locate or communicate with the known plan sponsor and have received no objection {*provide an explanation below*}:

_____

_____

_____

Part I – Plan Information

1. Estimated number of individuals (participants and beneficiaries) with accounts under the plan as of {*insert date*}: [*number*]
2. Plan assets held by Qualified Termination Administrator:
   - A. Estimated value of assets as of {*insert date*}: [*value*]
   - B. Months we have held plan assets, if less than 12: [*number*]
   - C. Hard to value assets {*select "yes" or "no" to identify any assets with no readily ascertainable fair market value, and include for those identified assets the best known estimate of their value*}:

		Yes	No	
(a)	Partnership/joint venture interests			[*value*]
(b)	Employer real property			[*value*]
(c)	Real estate (other than (b))			[*value*]
(d)	Employer securities			[*value*]
(e)	Participant loans			[*value*]
(f)	Loans (other than (e))			[*value*]
(g)	Tangible personal property			[*value*]

3. Name and last known address and telephone number of plan sponsor:

_____

_____

_____

4. Dollar amount of delinquent employer and employee contributions: {*Separately state employee and employer delinquent contributions.*}

_____

Part II – Known Service Providers of the Plan

Name	Address	Telephone
1.		
2.		
3.		

Part III – Services and Related Expenses to be Paid

Services	Service Provider	Estimated Cost
1.		
2.		
3.		

Part IV – Contact Person {*enter information only if different from signatory*}:

[*Name*]
[*Address*]
[*E-mail address*]
[*Telephone number*]

Under penalties of perjury, I declare that I have examined this notice and to the best of my knowledge and belief, it is true, correct and complete.

[*Signature*]
[*Title of person signing on behalf the Qualified Termination Administrator*] [*Address, e-mail address, and telephone number*]

Appendix C to Part 2578—Model Notice of Intent To Serve as Qualified Termination Administrator (for Plans Deemed Abandoned Pursuant to 29 CFR 2578.1(j)(2))

NOTIFICATION OF INTENT TO SERVE AS QUALIFIED TERMINATION ADMINISTRATOR

[*Date of notice*]

Abandoned Plan Coordinator
Office of Enforcement
Employee Benefits Security Administration
U.S. Department of Labor
200 Constitution Ave., NW, Suite 600
Washington, DC, 20210

Re:	Plan Identification	Qualified Termination Administrator
	[*Plan name and plan number*]	[N*ame*]
	[*EIN*]	[*Address*]
	[*Plan account number*]	[*E-mail address*]
	[*Address*]	[*Telephone number*]
	[*Telephone number*]	[*EIN*]

{*If applicable, include and complete the following pursuant to 29 CFR 2578.1(j)(6)(i) unless the same as Qualified Termination Administrator information above*}:

Bankruptcy Trustee
[*Name*]
[*Address*]
[*E-mail address*]
[*Telephone number*]

{Include below the plan sponsor's chapter 7 case number and bankruptcy court jurisdiction from the notice/order entered in the case reflecting the trustee's appointment. This information serves to link the plan with any fiduciary breach information reported by the bankruptcy trustee after the plan has been terminated and wound up.}

Case Number:_____
Bankruptcy Court Jurisdiction:_____

Abandoned Plan Coordinator:

Pursuant to 29 CFR 2578.1(j)(2), the subject plan is considered abandoned because the sponsor of the plan is in liquidation pursuant to a chapter 7 bankruptcy proceeding.

{*Insert as applicable*: [I have been appointed to administer the plan sponsor's case under chapter 7 of the U.S. Bankruptcy Code, and attached is a copy of the notice or order entered in the case reflecting my appointment. As the bankruptcy trustee administering this case, I am eligible to serve as Qualified Termination Administrator for purposes of terminating and winding up the plan in accordance with 29 CFR 2578.1, and hereby elect to do so.]

or

[A bankruptcy trustee has been appointed to administer the plan sponsor's case under chapter 7 of the U.S. Bankruptcy Code, and attached is a copy of the notice or order entered in the case reflecting the trustee's appointment. { [I] *o r* [We]} have been designated by the bankruptcy trustee and *{* [a m] *o r* [are]*}* eligible to serve as Qualified Termination Administrator for purposes of terminating and winding up the plan in accordance with 29 CFR 2578.1, and hereby elect to do so.]}

Part I – Plan Information

1. Estimated number of individuals (participants and beneficiaries) with accounts under the plan as of [*Insert date*]: [*number*]
2. Name, EIN, address and email address of the entity holding plan assets (if the entity is not the QTA):

_____

_____

_____

A. Estimated value of plan assets as of the date of the entry of an order for relief under chapter 7 of the U.S. Bankruptcy Code: [*value*]

B. Months entity has held plan assets, if less than 12: [*number*]

C. Hard to value assets {*select "yes" or "no" to identify any assets with no readily ascertainable fair market value, and include for those identified assets the best known estimate of their value*}*:*

		Yes	No	
(a)	Partnership/joint venture interests			[*value*]
(b)	Employer real property			[*value*]
(c)	Real estate (other than (b))			[*value*]
(d)	Employer securities			[*value*]
(e)	Participant loans			[*value*]
(f)	Loans (other than (e))			[*value*]
(g)	Tangible personal property			[*value*]

3. Name and last known address and telephone number of plan sponsor:

_____

_____

4. Dollar amount of delinquent employer and employee contributions:_____

_____

{*Separately state employee and employer delinquent contributions.*}

are described, below:

_____

_____

_____

Part II – Known Service Providers of the Plan

Name	Address	Telephone
1.		
2.		
3.		

Part III – Services and Related Expenses to be Paid

Services	Service Provider	Estimated Cost
1.		
2.		
3.		

Part IV – Contact Person {*enter information only if different from signatory*}:

[*Name*]
[*Address*]
[*E-mail address*]
[*Telephone number*]

Under penalties of perjury, I declare that I have examined this notice and to the best of my knowledge and belief, it is true, correct and complete.

[*Signature*]
[*Title of person signing on behalf the Qualified Termination Administrator*] [*Address, e-mail address, and telephone number*]

Appendix D to Part 2578—Model Notice of Plan Termination

NOTICE OF PLAN TERMINATION

[*Date of notice*]

[*Name and last known address of plan participant or beneficiary*]

Re: [*Name of plan*]

Dear [*Name of plan participant or beneficiary*]:

{*Insert as applicable* [We are] *or* [I am]} writing to inform you that the [*name of plan*] (Plan) has been terminated pursuant to regulations issued by the U.S. Department of Labor. The Plan was terminated because it was abandoned by [*name of the plan sponsor*]. {*For plans deemed abandoned pursuant to 29 CFR 2578.1(j)(2), replace the immediately preceding sentence with:* The Plan was terminated because [name of the plan sponsor] is in chapter 7 bankruptcy and the business is shutting down.}

We have determined that you have an interest in the Plan, either as a plan participant or beneficiary. Your account balance on [*date*] is/was [*account balance*]. We will be distributing this money as permitted under the terms of the Plan and federal regulations. The actual amount of your distribution may be more or less than the amount stated in this letter depending on investment gains or losses and the administrative cost of terminating the Plan and distributing your benefits.

Your distribution options under the Plan are {*add a description of the Retirement Plan's distribution options*}. It is very important that you elect one of these forms of distribution and inform us of your election. The process for informing us of this election is {*enter a description of the election process established by the qualified termination administrator*}.

{*Select the next paragraph from options 1 through 4, as appropriate.*}

{*Option 1: If this notice is for a participant or beneficiary, complete and include the following paragraph in cases in which the account balance will be distributed in accordance with the conditions of § 2550.404a–3(d)(1)(i) or (ii).*}

If you do not make an election within 30 days from your receipt of this notice, your account balance will be transferred directly to an individual retirement plan (inherited individual retirement plan in the case of a nonspouse beneficiary) maintained by {*insert the name, address, and phone number of the provider if known, otherwise insert the following language* [a bank or insurance company or other similar financial institution]}. Pursuant to federal law, money transferred to an individual retirement plan will be invested in an investment product designed to preserve principal and provide a reasonable rate of return and liquidity. {*If fee information is known, include the following sentence:* Should your money be transferred into an individual retirement plan, [*name of the financial institution*] charges the following fees for its services: {*add a statement of fees, if any, that will be paid from the participant or beneficiary's individual retirement plan*}.}

{*Option 2: If this notice is for a participant or beneficiary whose account balance will be distributed in accordance with the conditions of § 2550.404a–3(d)(1)(iii)), complete and include the following paragraph.*}

If you do not make an election within 30 days from your receipt of this notice, and your account balance is $1,000 or less, federal law permits us to transfer your

balance to {*insert whichever is applicable:* ''an interest-bearing federally insured bank account;'' ''an unclaimed property fund of the State of your last known address;'' *or* ''an individual retirement plan (inherited individual retirement plan in the case of a nonspouse beneficiary).''} {*If the transfer will be to an individual retirement plan, insert the following sentence:* Pursuant to federal law, your money would then be invested in an investment product designed to preserve principal and provide a reasonable rate of return and liquidity.} {*If known, include the name, address, and telephone number of the financial institution or State fund into which the individual's account balance will be transferred or deposited. If the individual's account balance is to be transferred to a financial institution and fee information is known, include the following sentence:* Should your money be transferred into {*insert whichever is applicable:* ''an individual retirement plan'' or ''bank account,'' [*name of the financial institution*] charges the following fees for its services: {*add a statement of fees, if any, that will be paid from the individual's account*}.}

{*Option 3: If this notice is for a participant or beneficiary whose account balance meets the conditions of § 2550.404a–3(d)(1)((iv), complete and include the following paragraph.*}

If you do not make an election within 30 days from your receipt of this notice, and your account balance is $1,000 or less, federal law permits us to transfer your balance to an individual retirement plan (inherited individual retirement plan in the case of a nonspouse beneficiary). Pursuant to federal law, your money, if transferred to an individual retirement plan would then be invested in an investment product designed to preserve principal and provide a reasonable rate of return and liquidity. However, if after exercising reasonable and good faith efforts, we cannot find an individual retirement plan provider who will accept your balance, we will transfer the balance to an interest-bearing federally insured bank account or to the unclaimed property fund of the State of your last known address. {*If the bankruptcy trustee or eligible designee knows where it will send the participant's or beneficiary's money, modify the preceding sentence accordingly and include the name, address, and telephone number of the financial institution or State fund into which the individual's account balance will be transferred or deposited. If the individual's account balance is to be transferred to a financial institution and fee information is known, include the following sentence:* Should your money be transferred into {*insert whichever is applicable:* ''an individual retirement plan'' or ''a bank account,''}, [*name of the financial institution*] charges the following fees for its services: {*add a statement of fees, if any, that will be paid from the individual's account*}.}

{*Option 4: If this notice is for a participant or participant's spouse who will be distributed an annuity under § 2578.1(d)(vii)(B)(2) to meet the survivor annuity requirements in sections 401(a)(11) and 417 of the Internal Revenue Code (or section 205 of ERISA), complete and include the following paragraph.*}

If you do not make an election within 30 days from your receipt of this notice, your account balance will be distributed in the form of a qualified joint and survivor annuity or qualified preretirement annuity as required by the Internal Revenue Code. {*If the name of the annuity provider is known, include the following sentence:* The name of the annuity provider is [*name, address and phone number of the provider*].}

For more information about the termination, your account balance, or distribution options, please contact [*name, address, and telephone number of the qualified termination administrator and, if different, the name, address, and telephone number of the appropriate contact person*].

Sincerely,

[*Name of qualified termination administrator or appropriate designee*]

[*Name of plan*]

Appendix E to Part 2578—Model Abandoned Plans Final Notice

FINAL NOTICE

[*Date of notice*]

Abandoned Plan Coordinator, Office of Enforcement
Employee Benefits Security Administration
U.S. Department of Labor
200 Constitution Ave., NW, Suite 600
Washington, DC, 20210

Re:	Plan Identification	Qualified Termination Administrator
	[Plan name, EIN and plan number from the plan's Form 5500]	[*Name*]
	[Plan account number]	[*Address and e-mail address*]
		[*Telephone number*]
		[*EIN*]

{*If applicable, complete and include the following pursuant to 29 CFR 2578.1(j)(6)(i) unless the same as Qualified Termination Administrator information above* }:

Bankruptcy Trustee
[*Name*]
[*Address*]
[*E-mail address*]
[*Telephone number*]

Abandoned Plan Coordinator:

General Information

The termination and winding-up process of the subject plan has been completed pursuant to 29 CFR 2578.1. Benefits were distributed to participants and beneficiaries on the basis of the best available information pursuant to 29 CFR 2578.1(d)(2)(i). Plan expenses were paid out of plan assets pursuant to 29 CFR 2578.1(d)(2)(v) and 29 CFR 2578.1(j)(7)(iv).

{*Include and complete the next section, entitled "Contact Person," only if the contact person is different from the signatory of this notice.*}

Contact Person

[*Name*]
[*Address and e-mail address*]
[*Telephone number*]

{*Include and complete the next section, entitled "Expenses Paid" only if fees and expenses paid by the plan exceeded by 20 percent or more the estimate required by 29 CFR 2578.1(c)(3)(v)(B) or 29 CFR 2578.1(j)(6)(vi)(B).*}

Expenses Paid

The actual fees and/or expenses paid in connection with winding up the Plan exceeded by

{*insert either*: [20 percent or more] *or* [*enter the actual percentage*]} the estimate required by 29 CFR 2578.1(c)(3)(v)(B) or 29 CFR 2578.1(j)(6)(vi)(B). The reason or reasons for such additional costs are {*provide an explanation of the additional costs*}

{*Include and complete next section, entitled "Delinquent Contributions," unless 100% of delinquent contributions were previously reported in the notification required by 29 CFR 2578.1 (c) or 2578.1(j)(6.)*}

Delinquent Contributions

Dollar amount of employee and employer contributions:_____

_____

_____

{*Separately state employee and employer delinquent contributions.*}

{*Include and complete the next section, entitled "other fiduciary breaches," if Qualified Termination Administrator, is a bankruptcy or an eligible designee, defined in 29 CFR 2578.1(j)(4)(ii), unless previously reported in the notification required by 29 CFR 2578.1(j)(6.)*}

Other Fiduciary Breaches

Activities evidencing breaches of fiduciary duty described in 29 CFR 2578.1(j)(7)(ii) are described, below.

{*Include and complete the next section, entitled "Distributions on Behalf of Deceased Participants and Beneficiaries," if distributions were made in accordance with 29 CFR 404a-3(d)(v).*}

Distributions on Behalf of Deceased Participants and Beneficiaries

We have made distributions permitted by 29 CFR404a-3(d)(v) and have reasonably and in good faith made the findings required by {*Insert whichever is applicable*: "29 CFR 404a-3(d)(v)(A) for distributions were made to a person other than the estate of the participant" *or* "29 CFR 404a-(3)(d)(v)(B) if distributions were made to the estate of the participant."} The summary of the findings required by 29 CFR 404a-3(d)(v)(C), including the basis for the findings and an attestation that we have the full name and last known address of the deceased participant, is attached.

Under penalties of perjury, I declare that I have examined this notice and to the best of my knowledge and belief, it is true, correct and complete.

[*Signature*]
[*Title of person signing on behalf the Qualified Termination Administrator*]
[*Address, e-mail address, and telephone number*]
Attachment

Signed at Washington, DC, this 22nd day of April, 2024.

Lisa M. Gomez,

Assistant Secretary, Employee Benefits Security Administration, U.S. Department of Labor.

[FR Doc. 2024–09029 Filed 5–16–24; 8:45 am]

BILLING CODE 4510–29–C

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2550

[Application Number D–11657]

ZRIN 1210–ZA20

Prohibited Transaction Exemption 2006–06 for Services Provided in Connection With the Termination of Abandoned Individual Account Plans

AGENCY: Employee Benefits Security Administration, Department of Labor.

ACTION: Exemption amendment.

SUMMARY: This document gives notice of an amendment to prohibited transaction exemption (PTE) 2006–06, a class exemption issued under the Employee Retirement Income Security Act of 1974 (ERISA). The exemption permits a ''qualified termination administrator'' (QTA) of an individual account pension plan that has been abandoned by its sponsoring employer to select itself to provide services to the plan in connection with the plan's termination and pay itself fees for the services. This amendment to PTE 2006–06 permits chapter 7 trustees who elect to be QTAs to rely on the exemption. This amendment to PTE 2006–06 also permits ''eligible designees'' of such chapter 7 trustees to rely on the exemption. The amendment is issued in connection with amendments to three related regulations under ERISA, published elsewhere in this issue of the **Federal Register**, that provide streamlined procedures for the termination of, and distribution of benefits from, abandoned individual account pension plans. The amendment would affect employee pension benefit plans (primarily small defined contribution plans), participants and beneficiaries of such plans, service providers, and individuals appointed to serve as bankruptcy trustees under chapter 7 of the U.S. Bankruptcy Code.

DATES: This amendment will be effective on July 16, 2024.

FOR FURTHER INFORMATION CONTACT: Susan Wilker, telephone (202) 693–8540, Office of Exemption Determinations, Employee Benefits Security Administration, U.S. Department of Labor (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

A. Summary Overview

On April 21, 2006, the Department of Labor issued three regulations that established the Employee Benefits Security Administration's (EBSA) Abandoned Plan Program to facilitate the orderly and efficient termination of, and distribution of benefits from, individual account pension plans that have been abandoned by their sponsoring employers.[1] The first regulation (the QTA Regulation) establishes standards for determining when individual account plans may be considered ''abandoned'' and procedures by which financial institutions, called ''qualified termination administrators'' (QTAs) holding the assets of such plans may terminate the plans and distribute benefits to participants and beneficiaries, with limited liability under Title I of the Employee Retirement Income Security Act (ERISA).[2] The second regulation (the Safe Harbor Regulation) provides a fiduciary safe harbor for QTAs to make distributions on behalf of participants and beneficiaries who fail to elect a form of benefit distribution. These participants and beneficiaries are sometimes referred to as ''missing participants.'' [3] The third regulation establishes a simplified method for filing a terminal report for abandoned individual account plans.[4]

The 2006 regulations were accompanied by a class prohibited transaction exemption, PTE 2006–06, that facilitates the goal of the 2006 regulations by permitting a QTA who meets the exemption's conditions to (1) select itself or an affiliate to carry out the termination and winding up activities specified in the 2006 regulations, and (2) pay fees to itself or an affiliate for those services. In addition, PTE 2006–06 permits QTAs to receive fees in connection with establishing an individual retirement plan or other account and selecting the initial investment product for missing participants. These activities are prohibited under the following provisions of Title I of ERISA (and parallel Code provisions) in the absence of a prohibited transaction exemption:

- ERISA section 406(a)(1)(C), which prohibits a plan fiduciary from causing the plan to engage in a transaction that constitutes a direct or indirect furnishing of goods, services, or facilities between the plan and a party in interest;
- ERISA section 406(a)(1)(D), which prohibits a fiduciary from entering into a transaction that constitutes a direct or indirect transfer of plan assets to a party in interest, or the use of plan assets by or for the benefit of a party in interest;
- ERISA section 406(b)(1), which prohibits a plan fiduciary from dealing with the assets of the plan in the fiduciary's own interest or for the fiduciary's own account; and
- ERISA section 406(b)(2), which prohibits a plan fiduciary from acting, in any transaction involving the plan, on behalf of a party (or representing a party) whose interests are adverse to the interests of the plan or its participants or beneficiaries.

On December 12, 2012, the Department published proposed amendments to the 2006 regulations and the associated PTE 2006–06.[5] The purpose of proposed amendments to the 2006 regulations was to advance the interests of participants and beneficiaries by:

(1) facilitating the orderly and efficient termination of individual account plans whose sponsors are in liquidation under chapter 7 of the Bankruptcy Code (''Chapter 7 ERISA Plans''); [6]

(2) reducing administrative burden and costs imposed on Chapter 7 ERISA Plan Plans that terminate in accordance with the regulations; and

(3) providing an avenue for bankruptcy trustees to discharge their duties under ERISA and the Bankruptcy Code with respect to Chapter 7 ERISA Plans.

The purpose of the proposed amendments to PTE 2006–06 was to supplement the amendments to the 2006 regulations by providing the necessary prohibited transaction relief to facilitate the termination of Chapter 7 ERISA Plans.

The Department received seven written comment letters on the 2012 proposed amendments, several of which raised issues related to the proposed amendment to PTE 2006–06 that are

[1] 71 FR 20820. *See also,* 73 FR 58459 (Oct. 7, 2008) for subsequent amendments with regard to distributions on behalf of a missing non-spouse beneficiary.

[2] 29 CFR 2578.1.

[3] 29 CFR 2550.404a–3. This safe harbor also is available to fiduciaries of terminated individual account plans that are not abandoned.

[4] 29 CFR 2520.103–13.

[5] 77 FR 74063; 77 FR 74056.

[6] The proposal referred to these plans as ''chapter 7 plans.'' The new term ''Chapter 7 ERISA Plans'' is used for avoidance of confusion regarding the term chapter 7 plan used in the bankruptcy context.

available on the Department's website.[7] The Department considered the issues raised by the commenters in granting this amendment to PTE 2006–06. The Department also issued interim final amendments to the 2006 regulations with a request for comment (referred to as the ''Regulations'')[8] that appear elsewhere in this issue of the **Federal Register**.

In granting this amendment to PTE 2006–06, the Department has determined that the amendment is administratively feasible, in the interests of plans and their participants and beneficiaries, and protective of the rights of plan participants and beneficiaries as required by ERISA section 408(a) and Internal Revenue Code (Code) section 4975(c)(2).[9]

B. Fiduciary Status of Bankruptcy Trustees and Prohibited Transactions

In bankruptcy cases, as with abandoned plans generally, the sponsor usually is not in a position to carry out the activities associated with formally terminating the plan. Instead, the Department expected that, in chapter 7 bankruptcy cases, the appointed bankruptcy trustee would take the necessary steps to terminate the plan, wind up its affairs, and distribute plan benefits. The issue of the bankruptcy trustee's authority to terminate and wind up the plan was addressed by the enactment of 11 U.S.C. 704(a)(11) as part of the Bankruptcy Abuse Prevention and Consumer Protection Act of 2005.[10] Under that provision, when an entity that sponsors an individual account plan is liquidated under chapter 7 of the Bankruptcy Code, the appointed bankruptcy trustee administering the liquidation proceeding is required to continue to perform the plan administration obligations that would otherwise be required of the bankrupt entity.[11]

Such obligations include taking the steps necessary to terminate the plan, wind up the affairs of the plan, and distribute plan benefits to participants and beneficiaries. A bankruptcy trustee who undertakes these plan responsibilities is a fiduciary within the meaning of ERISA section 3(21)[12] who is obligated under ERISA section 404 to act prudently and solely in the interests of plan participants and beneficiaries.

The Department has concluded that expanding the Abandoned Plan Program regulations to cover Chapter 7 ERISA Plans and making other technical changes in response to the public comments would result in an improved Abandoned Plan Program. The Department acknowledges that it has been over 10 years since the comment period closed for the 2012 proposal. However, the purposes of the Department's regulatory action and its rationale for the 2012 proposal continue to be relevant and would advance the interests of participants and beneficiaries in abandoned plans. The Department is relying on the 2012 proposal, its consideration of comments on that proposal, and its understanding of the challenges facing Chapter 7 ERISA Plans in granting this exemption. Although, the procedures and requirements in the program are voluntary, in the Department's view, a bankruptcy trustee that follows the Regulations should generally be able to reduce its administrative burden and costs that are associated with terminating an abandoned plan.

C. Description of the Amendment

1. Summary of Major Changes in This Granted Exemption Amendment

This amendment to PTE 2006–06 expands the types of service providers that are eligible to serve as QTAs to include bankruptcy trustees and entities designated by bankruptcy trustees to terminate and wind up the affairs of plans according to the Regulations (referred to as ''eligible designees''). This amendment would permit these parties to rely on PTE 2006–06 to select and pay themselves fees for services provided in terminating and winding up the affairs of a plan. Furthermore, for the accounts of missing participants of an abandoned plan, the amendment will permit certain eligible designees to select themselves or an Affiliate[13] (and receive fees) to establish an Individual Retirement Plan[14] or other account and to select the initial investment product. The prohibited transaction relief provided by the exemption is available only if the exemption conditions are satisfied, which are designed to protect the interests of the plans and their participants and beneficiaries as required by ERISA section 408(a) and Code section 4975(c)(2).

2. Definition of ''Qualified Termination Administrator''

To be a QTA that is eligible for the prohibited transaction relief under the original version of PTE 2006–06, an entity was required to (i) be eligible to serve as a trustee or issuer of an individual retirement plan or other account, within the meaning of Code section 7701(a)(37) and (ii) hold assets of the plan that is considered abandoned. Bankruptcy trustees ordinarily would not be eligible for the exemptive relief as QTAs under this definition.

As noted above, the Regulations are amended elsewhere in this issue of the **Federal Register** to include bankruptcy trustees and their eligible designees. Therefore, the final amendment likewise expands the exemption's QTA definition to include a bankruptcy trustee in a liquidation proceeding under chapter 7 of title 11 of the United States Code with responsibility under 11 U.S.C. 704(a)(11) to administer one or more individual account plans sponsored by the entity that is the subject of the proceeding, who elects to be a QTA under 29 CFR 2578.1(j)(6).[15]

The Regulations expand the group of entities that can serve as a QTA by

[7] Available at *https://www.dol.gov/agencies/ebsa/laws-and-regulations/rules-and-regulations/public-comments/1210-AB47.*

[8] The Department intends that PTE 2006–06 will cover transactions related to the interim final regulations or any subsequent final regulations published thereafter. The Department will consider proposing an additional amendment to PTE 2006–06 if it makes changes to the Abandoned Plan Program that impact the relief available under this exemption.

[9] Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978, 5 U.S.C. App. (2018), transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor. Therefore, this amendment is issued solely by the Department.

[10] Public Law 109–8, 119 Stat. 23.

[11] 11 U.S.C. 704(a)(11) refers to whether the debtor (or any entity designated by the debtor) serves as the administrator (as defined in ERISA section 3) of an employee benefit plan. ERISA section 3(16) defines the ''administrator'' as the plan sponsor in the absence of any designation in the plan document of another person as administrator.

[12] In this regard, section 3(21)(A)(i) of ERISA provides that a person is a ''fiduciary'' with respect to a plan to the extent he exercises any discretionary authority or discretionary control respecting management of such plan or exercises any authority or control respecting management or disposition of its assets. In addition, section 3(21)(A)(iii) of ERISA provides that a person is a ''fiduciary'' with respect to a plan to the extent he has any discretionary authority or discretionary responsibility in the administration of such plan.

[13] Affiliate is defined to include: (1) Any person directly or indirectly controlling, controlled by, or under common control with, the person; or (2) Any officer, director, partner or employee of the person. The terms ''controlling, controlled by, or under common control'' means the power to exercise a controlling influence over the management or policies of a person other than an individual. *See* Sections V(e) and V(f) of this exemption amendment.

[14] Section V(b) of this exemption defines Individual Retirement Plan to mean: an individual retirement plan described in section 7701(a)(37) of the Code. For purposes of Section III of this exemption, the term ''Individual Retirement Plan'' shall also include an inherited individual retirement plan (within the meaning of section 402(c)(11) of the Code) established to receive a distribution on behalf of a non-spouse beneficiary. Notwithstanding the foregoing, the term ''Individual Retirement Plan'' shall not include an employee benefit plan covered by Title I of ERISA.

[15] Eligible designees are defined in 29 CFR 2578.1(j)(4)(i) and (ii).

allowing the bankruptcy trustee to also appoint as an eligible designee either a traditional asset custodian or a person, other than the bankruptcy trustee of the plan sponsor's case, who has served within the previous five years as a bankruptcy trustee in a case under chapter 7 of the Bankruptcy Code (referred to as the ''independent bankruptcy trustee practitioner''). This amendment correspondingly expands the prohibited transaction relief in PTE 2006–06 by including these ''eligible designees'' in the exemption's definition of QTA.[16]

The Department also added a new clarification which indicates that if a bankruptcy trustee designates an eligible designee, it shall not be considered a QTA with respect to the relief provided in this exemption. The Department is making this additional modification to the QTA definition because the QTA Regulation considers the bankruptcy trustee and the eligible designee to be the QTA for certain purposes.[17] In connection with the exemption, however, the Department determined that once an eligible designee is appointed, the eligible designee should be the only entity authorizing appropriate payments to the bankruptcy trustee.

3. The ''Designating Bankruptcy Trustee''

The amendment includes a new defined term for a ''Designating Bankruptcy Trustee.'' [18] A Designating Bankruptcy Trustee is a bankruptcy trustee that designates an eligible designee instead of serving as the QTA itself.[19] Importantly, this amendment would allow the Designating Bankruptcy Trustee to provide services to the plan before designating an eligible designee. These services could include making reasonable and diligent efforts to determine whether the plan is owed any employee or employer contributions, notifying the eligible designee of its findings with respect to missing or delinquent contributions, establishing procedures to ensure the eligible designee has reasonable access to records in possession of the bankruptcy trustee which are needed to wind up the plan, selecting an eligible designee, and subsequently monitoring eligible designees in accordance with ERISA section 404(a)(1)(A) and (B). As noted in the QTA Regulation, the duty to monitor the eligible designee is ongoing throughout the termination and winding up process.

From a prohibited transaction standpoint, the Department determined there may be uncertainty regarding an eligible designee's decision to pay the Designating Bankruptcy Trustee with plan assets. This is due, at least in part, to the role of the bankruptcy trustee in the QTA Regulation. To avoid this uncertainty and facilitate the use of the Abandoned Plan Program and PTE 2006–06 when an eligible designee is selected, this amendment includes specific prohibited transaction relief for this scenario that is described in the next section, below.

4. Covered Transactions and Conditions—Overview

The prohibited transaction relief provided by the amended exemption would permit four general categories of transactions in connection with termination services. First, it would permit the QTA to select itself or an Affiliate to provide services to the plan. Second, it would permit the QTA to pay fees to itself or an Affiliate for those services. Third, it would permit the QTA to pay fees to itself for services provided before the plan's deemed termination.[20] Finally, it would permit the QTA to pay fees to a Designating Bankruptcy Trustee for services provided to the plan. Without the availability of the prohibited transaction exemption, QTAs, their Affiliates, and bankruptcy trustees would be unable to use plan assets as a source of compensation for their services, even though those plan assets are usually the only available source of payment.

The amended exemption would also permit certain distribution transactions. First, an asset custodian QTA could designate itself or an Affiliate as the provider of an Individual Retirement Plan, other account, or a federally insured bank or savings association account for the distribution of benefits if participants and beneficiaries do not respond to the QTA regarding how they would like their benefits distributed.[21] Second, the amended exemption would permit the asset custodian QTA to select a proprietary investment product as the initial investment in connection with such distributions. Third, the QTA or its Affiliate may receive fees in connection with establishing and maintaining the Individual Retirement Plan or other account. Fourth, the QTA may pay investment fees to itself or an Affiliate as a result of investment in a qualifying proprietary investment product.

(a) Termination Services and Payment of Fees—Generally

Section I(a) of the amended exemption provides prohibited transaction relief for a QTA to select and pay itself fees for services to the plan, subject to the conditions in Sections II and IV.[22] Generally, the exemption would permit a QTA to use its authority to select itself or an Affiliate to provide services to the plan and to pay itself or an Affiliate fees for services performed as the QTA. Prohibited transaction relief under Section I(a) is available to all entities that may serve as a QTA according to the QTA Regulation. Therefore, if the applicable conditions are satisfied, a bankruptcy trustee could select itself to be the QTA and also pay itself for the QTA services it provides to the plan. Similarly, if the bankruptcy trustee appoints an eligible designee to be the QTA, the eligible designee could pay itself for services it provides to the plan.

The amended exemption also provides prohibited transaction relief for plan-related services provided by a bankruptcy trustee before a formal determination is made regarding who will be the QTA.[23] If the bankruptcy trustee becomes the QTA, the exemption would permit the bankruptcy trustee to pay itself for the non-QTA services that were performed before it becomes the QTA. The Department provides this relief to ensure that necessary plan services can continue to be performed while a decision is made regarding the selection of a QTA. Relatedly, the amended exemption also permits the eligible designee to pay the bankruptcy trustee for services provided

[16] *See* Section V(a) of this exemption amendment.

[17] *See* 29 CFR 2578.1(e)(4).

[18] *See* Section V(h) of this exemption amendment.

[19] As noted above, the QTA Regulation indicates that the bankruptcy trustee and eligible designee are both considered the QTA for certain purposes. The Department's limitations with respect to the bankruptcy trustee being considered the QTA for purposes of this exemption do not modify or otherwise supersede the QTA Regulation.

[20] *See* 29 CFR 2578.1(c).

[21] As explained in more detail below with respect to Section I(b), this prohibited transaction relief is available only to eligible designee QTAs that are asset custodians. It is not available for QTAs that are bankruptcy trustees. It is also not available for eligible designees that are independent bankruptcy trustee practitioners.

[22] Section I(a) provides prohibited transaction relief for ERISA sections 406(a)(1)(A) through (D), 406(b)(1), and 406(b)(2) and the taxes imposed by Code section 4975(a) and (b) by reason of Code section 4975(c)(1)(A) through (E).

[23] As noted above and described in the QTA Regulation, these services include making reasonable and diligent efforts to determine whether the plan is owed any employee or employer contributions, notifying the eligible designee of its findings with respect to missing or delinquent contributions, establishing procedures to ensure the eligible designee has reasonable access to records in possession of the bankruptcy trustee which are needed to wind up the plan, and selecting and monitoring eligible designees in accordance with ERISA section 404(a)(1)(A) and (B).

to the plan if the eligible designee is the QTA. This includes paying the bankruptcy trustee for services provided to the plan before the eligible designee provided notice to the Department of its intention to serve as QTA [24] or for ongoing services provided after the notice is submitted (such as monitoring the QTA).

Section II of the amended exemption includes conditions for covered termination services and the corresponding receipt of fees. Section II(a) provides prohibited transaction relief only if the requirements of the QTA Regulation are satisfied. Section II(b) provides that when the QTA, its Affiliate, and any Designating Bankruptcy Trustee are paid fees and expenses, they must comply with the applicable provisions regarding reasonable expenses of the QTA Regulation. Therefore, for QTAs that are not chapter 7 bankruptcy trustees or their eligible designees, the exemption cross references paragraph (d)(2)(v)(B)(2)(i) and (ii) of the QTA Regulation. For chapter 7 bankruptcy trustee QTAs and their eligible designees, the exemption cross references paragraph (j)(7)(iv) of the QTA Regulation.[25]

The fee provisions in the QTA Regulation generally provide that plan assets may be used to pay reasonable expenses of plan termination. What is reasonable is judged in light of industry rates for ordinary plan administration under ERISA.[26] Consequently, these provisions do not allow a bankruptcy trustee or eligible designee to charge attorney hourly rates for plan administration activities of termination and winding up the plan.

The QTA Regulation contains a limited exception to the general rule regarding fees that would apply to services provided by the eligible designee in connection with the duty to collect delinquent contributions on behalf of the plan. Under the exception, the fees must be consistent with rates ordinarily charged by firms or individuals representing or assisting a bankruptcy trustee in performing similar collection services on behalf of an estate in a chapter 7 proceeding. This limited exception applies to activities such as filing proofs of claims, tracing assets, responding to objections, motion practice, and litigation on behalf of the plan, but it does not apply to determining whether the plan is owed contributions. The act of determining whether a plan is owed a contribution is a routine act of plan administration and is therefore covered under the general rule rather than the exception.

(b) Termination Services and Payment of Fees—Before Notice of Intent To Serve as QTA

Additional conditions apply to transactions in which a QTA pays itself fees for services provided to a plan before submitting notice to the Department of its intent to act as the QTA.[27] Section II(c) requires any such services to be performed in good faith according to an executed written agreement or otherwise in full compliance with the QTA Regulation. The QTA must represent under penalty of perjury that such services were actually performed and/or will actually be performed (in the case of services provided after notice but before deemed termination). This condition specifically requires a prospective representation for such services in the notice of intent to serve as QTA.[28] The Department believes this will avoid uncertainty as to services that will be performed after notice is provided to the Department but before the deemed termination. If past services were performed according to a contract, a copy of the executed contract that authorized such services must be provided to the Department along with the notice.

For transactions in which the eligible designee QTA pays the Designating Bankruptcy Trustee, the exemption requires the services to be performed by the Designating Bankruptcy Trustee in full compliance with the QTA Regulation. Additionally, the Designating Bankruptcy Trustee must represent under penalty of perjury that the services were actually performed and/or will actually be performed (in the case of services provided after notice but before deemed termination). The Designating Bankruptcy Trustee must provide this written representation to the QTA for the QTA to submit to the Department.

(c) Distribution Transactions

Section I(b) provides prohibited transaction relief for an asset custodian QTA to designate itself or an Affiliate as the provider of an Individual Retirement Plan, other account, or a federally insured bank or savings association account for the distribution of benefits.[29] Section I(b) is available only to eligible designees that are asset custodians and QTAs, as defined in section V(a)(1) and V(a)(2)(ii) of this amendment. The relief in Section I(b) is not available to QTAs that are bankruptcy trustees or independent bankruptcy trustee practitioners. In the 2012 proposed exemption amendment, the Department noted that bankruptcy trustees do not maintain proprietary investment vehicles; thus, the relief in Section I(b) was not proposed to extend to bankruptcy trustees. The Department did not receive comments on this issue with respect to the 2012 proposed exemption amendment, so the Department has maintained the same scope of relief in Section I(b) of this amendment.

Generally, the prohibited transaction relief in Section I(b) applies only if the participant or beneficiary has otherwise failed to notify the QTA regarding how they want to take their distribution. The relief in Section I(b) is subject to the additional conditions of Sections III and IV. More specifically, Section I(b) permits a QTA to use its authority in connection with the termination of an abandoned individual account plan to designate itself or an Affiliate as the service provider of (1) an Individual Retirement Plan, (2) an inherited Individual Retirement Plan in the case of a distribution on behalf of a non-spouse beneficiary as described in paragraph (d)(1)(ii) of the Safe Harbor Regulation, or (3) an interest bearing, federally insured bank or savings association account for a distribution described in paragraph (d)(1)(iii) of the Safe Harbor Regulation.[30]

Section I(b) also permits a QTA to engage in certain activities in connection with establishing an Individual Retirement Plan or other account. First, the QTA may make the initial investment of a participant's or beneficiary's account balance in its or its Affiliate's propriety investment product. Second, the QTA or its Affiliate may receive fees in connection

[24] *See* 29 CFR 2578.1(j)(6).

[25] This amendment cross references these provisions instead of restating them to avoid any potential confusion regarding the standards and to accommodate future amendments to the QTA Regulation that would not otherwise require an amendment to PTE 2006–06. If, in the future, the Department makes changes to the QTA Regulation in the cross-referenced provisions, the Department will consider whether the statutory exemption requirements in ERISA section 408(a) and Code section 4975(c)(2) necessitate proposing an amendment to the exemption.

[26] *See* 29 CFR 2578.1(d)(2)(v).

[27] *See* Section I(a)(3) of this exemption amendment.

[28] *See* paragraph 29 CFR 2578.1(c)(3) of the QTA Regulation or in the case of a QTA described in Section V(a)(2)(i) of this exemption, 29 CFR 2578.1(j)(6).

[29] Section I(b) of the amended exemption provides relief from the restrictions of ERISA sections 406(a)(1)(A) through (D), 406(b)(1), and 406(b)(2) and the taxes imposed by Code section 4975(a) and (b) by reason of Code section 4975(c)(1)(A) through (E).

[30] *See* 29 CFR 2550.404a–3.

with establishing and maintaining the Individual Retirement Plan or other account. Third, the QTA may pay investment fees to itself or an Affiliate as a result of investment in a proprietary investment product that qualifies as an Eligible Investment Product defined in Section V(c).

Section III provides conditions for the transactions described in Section I(b) and was not altered by the 2012 proposed exemption amendment. This final amendment makes minor ministerial changes to Section III, such as the addition of headings to facilitate the ease of use of the exemption.

Section III(a) requires compliance with the QTA Regulation, and Section III(b) requires additional notifications to participants or beneficiaries to accompany the notice to participants and beneficiaries described in the QTA Regulation.[31] Section III(c) requires each Individual Retirement Plan or other account to be established and maintained for the exclusive benefit of the Individual Retirement Plan account holder or other account holder or their beneficiaries. This requirement is consistent with Code section 408(a) and ensures that the establishment of such plans or accounts does not conflict with the basic purpose for which Congress afforded them special tax benefits (*i.e.,* to provide retirement savings for account holders and their beneficiaries).

Section III(d) requires the terms of the Individual Retirement Plan or other account to be no less favorable than those available to comparable Individual Retirement Plans or other accounts established for reasons other than the receipt of a rollover distribution described in the QTA Regulation. This exemption condition applies to all terms, including the fees and expenses for establishing and maintaining the Individual Retirement Plan or other account.

Section III(e) requires distributions to be invested in an Eligible Investment Product as defined in section V(c) of this amendment.[32] The definition of Eligible Investment Product was not changed as part of this amendment.

Section III(f) requires the rate of return or investment performance of plans or accounts established in connection with QTA Regulation to be the same as other similar type of plans or accounts. This condition was designed to work in tandem with the requirement in Section III(d). It ensures fees are not hidden within separately designed investment products provided only to plans or accounts established under the QTA Regulation.

Example 1: Assume a customer opens a new Individual Retirement Plan and invests in a one-year certificate of deposit that returns 2.0%. The one-year certificate of deposit that returns 2.0% is also available to an Individual Retirement Plan established at the same time in accordance with the QTA Regulation. This is a permissible investment option.

Example 2: Assume a customer opens a new Individual Retirement Plan and invests in a one-year certificate of deposit that returns 2.0%. For Individual Retirement Plans established under the QTA Regulation, all certificates of deposit have a 5% lower return so that the one-year certificate of deposit only returns 1.9%. This is *not* a permissible investment option.

Section III(g) does not permit the Individual Retirement Plan or other account to pay a sales commission in connection with the acquisition of an Eligible Investment Product. Furthermore, Section III(h) indicates that the Individual Retirement Plan account holder or other account holder must be able to transfer their account balance to a different investment offered by the QTA or its Affiliate within a reasonable period of time after their request. In connection with the request, the QTA or its Affiliate may not assess any penalty against the principal amount of the account balance. According to those same standards, the Individual Retirement Plan account holder or other account holder must be able to transfer their account balance to an Individual Retirement Plan established with a different financial institution.

Finally, Section III(i) includes restrictions on fees and expenses associated with the Individual Retirement Plan or other account including with respect to investment of assets. This provision requires equal treatment for any such charges, which includes but is not limited to: establishment charges, maintenance fees, investment expenses, termination costs, and surrender charges. The fees and expenses may not exceed those charged by the QTA for comparable Individual Retirement Plans or other accounts established for reasons other than the receipt of a rollover distribution made pursuant to the QTA Regulation. Relatedly, fees and expenses associated with the Individual Retirement Plan or other account, other than establishment charges, may be charged only against the income earned by the Individual Retirement Plan or other account and may not be charged against principal. Finally, fees and expenses may not exceed reasonable compensation within the meaning of Code section 4975(d)(2).

5. Recordkeeping

Section IV of the amended exemption contains a recordkeeping requirement that is mostly unchanged from the proposed amendment. The Department made a minor modification in Section IV(a) by replacing the phrase ''determination of plan abandonment and its election'' with ''intent'' so that the recordkeeping requirement clearly applies to the new categories of QTAs (*i.e.,* chapter 7 bankruptcy trustees and eligible designees). Ultimately, this means that any party serving as a QTA must maintain records to enable certain persons to determine whether the applicable conditions of the class exemption have been satisfied. The records must be available for examination by the Department of the Treasury, the Department, and any account holder of an Individual Retirement Plan or other account established pursuant to this exemption or any duly authorized representative of such account holder.

D. Other Ministerial Changes

The Department is also making a few ministerial changes to the exemption that will not substantively alter the conditions or relief provided under the exemption. Specifically, the Department has capitalized most of the defined terms, added the word ''Section'' to each section, modified the text of the headings slightly, added headings in Sections II and III to facilitate ease of use of the exemption, and made other edits to improve readability. The Department also removed the reference to ''spouse'' in Section III(c) because the

[31] See 29 CFR 2578.1(d)(2)(vi).

[32] This is an investment product designed to preserve principal and provide a reasonable rate of return, whether or not such return is guaranteed, consistent with liquidity. For this purpose, the product must be offered by a Regulated Financial Institution and shall seek to maintain, over the term of the investment, the dollar value that is equal to the amount invested in the product by the Individual Retirement Plan or other account. An Eligible Investment Product includes money market funds maintained by registered investment companies, and interest-bearing savings accounts and certificates of deposit of a bank or similar financial institution. In addition, it would also include ''stable value products'' issued by a financial institution that are fully benefit-responsive to the Individual Retirement Plan account holder or other account holder (*i.e.,* that provide a liquidity guarantee by a financially responsible third party of principal and previously accrued interest for liquidations or transfers initiated by the Individual Retirement Plan account holder or other account holder exercising their right to withdraw or transfer funds under the terms of an arrangement that does not include substantial restrictions to the account holder to access the Individual Retirement Plan or other account's assets).

exclusive benefit rule in Code section 408(a) does not separately reference a spouse.

E. Discussion of Comments

While the Department did not receive any comments on the 2012 proposed amendment's expansion to bankruptcy trustees, it received several comments on other aspects of the 2012 proposed amendment. One commenter requested elimination of a condition in the exemption limiting the amount of fees and expenses that may be charged when a QTA recommends itself or an affiliate as a provider of an Individual Retirement Plan or other account. The condition in Section III(i)(2) requires fees and expenses charged to the Individual Retirement Plan or other account may only be taken from the income earned by the Individual Retirement Plan or other account with the exception of establishment charges.

The Department considered a similar request to remove Section III(i)(2) when it first granted PTE 2006–06. The Department continues to believe that removal of this condition is not warranted because the Regulations provide significant flexibility for small account balances to be distributed by methods other than through a rollover to an Individual Retirement Plan or other account sponsored by the QTA or its affiliate. For example, participant account balances of $1,000 or less that are below the minimum amount required for investment in the QTA's Individual Retirement Plan investment product may be distributed to: (i) an interest-bearing federally insured bank or savings association account in the name of the participant or beneficiary; (ii) the unclaimed property fund of the State in which the participant's or beneficiary's last known address is located; or (iii) to an unaffiliated Individual Retirement Plan if the Individual Retirement Plan is also offered to the public at the time of the distribution. The Department continues to believe that Section III(i)(2) is necessary to preserve the principal balance of missing and non-responsive participants and beneficiaries (consistent with protecting the retirement savings for participants and their beneficiaries). Section III(i)(2) also provides a valuable safeguard against potential conflicts of interest associated with a QTA's selection of its own or its affiliate's Individual Retirement Plan or account and initial investment product.

Another commenter requested clarification that providers of Individual Retirement Plans or investment accounts who are not affiliated or related to a QTA and accept distribution accounts from a QTA into their own proprietary investment products, are not subject to the same fee and expense restrictions described in Section III(i)(2) of the exemption. The Department responds that the scenario described by the commenter does not appear to involve a prohibited transaction, and parties only are required to rely on the exemption (including complying with Section III(i)(2)) if the receipt of compensation in connection with these transactions involves a prohibited transaction.

F. Regulatory Impact Analysis

1. Background and Need for Regulatory Action

As stated earlier in this preamble, this document contains an amendment to PTE 2006–06 which expands the types of service providers that are eligible to serve as QTAs to include bankruptcy trustees and entities designated by bankruptcy trustees to terminate and wind up the affairs of plans according to the Regulations that facilitate the termination of, and distribution of benefits from, individual account pension plans that have been abandoned by their sponsoring employers. The need for the amendments is explained in detail above in this preamble, as well as the preamble to the 2012 proposal and preamble to the Regulations that appear elsewhere in this issue of the **Federal Register**.

The Department has examined the effects of these amendments as required by Executive Order 12866,[33] Executive Order 13563,[34] the Congressional Review Act,[35] the Paperwork Reduction Act of 1995,[36] the Regulatory Flexibility Act,[37] section 202 of the Unfunded Mandates Reform Act of 1995,[38] and Executive Order 13132.[39]

2. Executive Orders 12866 and 13563 Statement

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing and streamlining rules, and of promoting flexibility. It also requires federal agencies to develop a plan under which the agencies will periodically review their existing significant regulations to make the agencies' regulatory programs more effective or less burdensome in achieving their regulatory objectives. The Department identified the amendments to the 2006 regulations as part of a retrospective regulatory review project consistent with the principles of Executive Order 13563. The changes will improve the overall efficiency of the program established under the 2006 regulations, increase its usage, and substantially reduce burdens and costs on bankruptcy trustees (or their designees) terminating the plans of sponsors in chapter 7 liquidation, the plans of bankrupt sponsors, and the participants in these plans.

Under Executive Order 12866, ''significant'' regulatory actions are subject to the requirements of the executive order and review by the Office of Management and Budget (OMB). As amended by Executive Order 14094 [40] entitled ''Modernizing Regulatory Review,'' section 3(f) of the executive order 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 $200 million or more (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) creating 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 legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

3. Affected Entities

The group of entities affected by the amendments consists of affected abandoned plans as defined under the 2006 regulations, Chapter 7 ERISA Plans

[33] Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993).

[34] Improving Regulation and Regulatory Review, 76 FR 3821 (Jan. 21, 2011).

[35] 5 U.S.C. 804(2) (1996).

[36] 44 U.S.C. 3506(c)(2)(A) (1995).

[37] 5 U.S.C. 601 *et seq.* (1980).

[38] 2 U.S.C. 1501 *et seq.* (1995).

[39] Federalism, 64 FR 43255 (Aug. 10, 1999).

[40] 88 FR 21879 (April 6, 2023).

newly eligible to utilize the abandoned plan rules, and the financial firms and bankruptcy trustees who serve as QTAs.

4. Benefits

The key benefit of the amendment to PTE 2006–06 is facilitation of the benefits provided by the Regulations, as explained in the Regulatory Impact Analysis that accompanies the Regulations, published elsewhere in this issue of the **Federal Register**. Without the accompanying amendment to PTE 2006–06, certain of the benefits of the Regulations may be impeded due to the existence of prohibited transactions.

5. Costs

The cost of the amendment to PTE 2006–06 is captured in the Regulatory Impact Analysis that accompanies the Regulations, published elsewhere in this issue of the **Federal Register**. The only additional cost associated with this amendment to PTE 2006–06 is related to a new condition that is applicable in cases where a Designating Bankruptcy Trustees provides services to the plan. In that situation, the Designating Bankruptcy Trustee must represent under penalty of perjury that such services were actually performed and/or will actually be performed and provide the QTA with such representation for the QTA to provide to the Department in the notice of intent to serve as qualified termination administrator. As noted in the Paperwork Reduction Act section of the preamble to the Regulations, the Department did not include a cost burden for this new condition because it is expected to be de minimis and included in other notices sent to the Department.

G. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), the Department solicited comments concerning the information collection requirements (ICRs) included in the December 12, 2012, proposed amendments to the 2006 regulations at 77 FR 74063 and the proposed amendments to the class exemption PTE 2006–06 at 77 FR 74055. At the same time, the Department also submitted the ICR to OMB in accordance with 44 U.S.C. 3507(d).

The amendment to PTE 2006–06 would only be used by QTAs that also take advantage of the amendments to the Regulations, published elsewhere in this issue of the **Federal Register**. The Department has combined the hour and cost burdens associated with the proposed amendment to PTE 2006–06 with the hour and cost burden associated with the Regulations, under existing OMB Control Number 1210–0127.

By using a single ICR, the Department believes that the regulated community will gain a better understanding of the overall burden impact of terminating abandoned plans pursuant to the amendments. The specific burden for PTE 2006–06 includes the penalty of perjury statements required to be submitted by the QTA and/or Designating Bankruptcy Trustee and a recordkeeping requirement for QTAs. The hour and cost burden for the ICR is described more fully in the preamble to the Regulations under the Paperwork Reduction Act section. A copy of the ICR for OMB Control Number 1210–0127 may be obtained by contacting the PRA addressee listed in the following sentence or at *www.RegInfo.gov.* For additional information, contact: James Butikofer, Office of Research and Analysis, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, Room N–5718, Washington, DC 20210; or *ebsa.opr@dol.gov.* The OMB will consider all comments that they receive on or before June 17, 2024. Comments and recommendations for the 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.

H. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) applies to most Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*). Unless an agency certifies that such a rule will not have a significant economic impact on a substantial number of small entities, section 603 of the RFA requires the agency to present a final regulatory flexibility analysis at the time of the publication of the rulemaking describing the impact of the rule on small entities. Small entities include small businesses, organizations, and governmental jurisdictions. For purposes of analysis under the RFA, the Department considers a small entity to be an employee benefit plan with fewer than 100 participants. The basis of this definition is found in section 104(a)(3) of ERISA, which permits the Secretary of Labor to prescribe simplified annual reports for welfare benefit plans that cover fewer than 100 participants. While some large employers may have small plans, in general, small employers maintain most small plans. Thus, the Department believes that assessing the impact of these final regulations on small plans is an appropriate substitute for evaluating the effect on small entities. The definition of small entity considered appropriate for this purpose differs, however, from a definition of small business that is based on size standards promulgated by the Small Business Administration (SBA) (13 CFR 121.201) pursuant to the Small Business Act (15 U.S.C. 631 *et seq.*). The Department requested comments on the appropriateness of this size standard at the proposed rule stage and received no adverse responses.

Due to the small number of small plans involved and relatively low cost per plan, the Assistant Secretary of the Employee Benefit Security Administration hereby certifies under 5 U.S.C. 605 that this amended exemption in combination with the Regulations will not have a significant economic impact on a substantial number of small entities.[41]

I. Congressional Review Act

This amendment is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and will be transmitted to the Congress and the Comptroller General for review. The exemption is not a ''major rule'' as that term is defined in 5 U.S.C. 804, because it is not likely to result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, or Federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

J. Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), the rule does not include any Federal mandate that will result in expenditures by state, local, or tribal governments in the aggregate of more than $100 million, adjusted for inflation, or increase expenditures by the private sector of more than $100 million, adjusted for inflation.

[41] 2,506 abandoned plans each year divided by the roughly 6 million establishments with less than 50 participants results in less than 0.05%.

K. Federalism Statement

Executive Order 13132 (August 4, 1999) outlines fundamental principles of federalism and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have substantial direct effects on the States, the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. This rule does not have federalism implications because it has no 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. Section 514 of ERISA provides, with certain exceptions specifically enumerated, that the provisions of Titles I and IV of ERISA supersede any and all laws of the States as they relate to any employee benefit plan covered under ERISA. The requirements implemented in the rule do not alter the fundamental provisions of the statute with respect to employee benefit plans, and as such would have no implications for the States or the relationship or distribution of power between the national government and the States.

L. General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under ERISA section 408(a) and Code section 4975(c)(2) does not relieve a fiduciary, or other party in interest or disqualified person with respect to a plan, from certain other provisions of ERISA and the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of ERISA section 404 which require, among other things, that a fiduciary act prudently and discharge their duties respecting the plan solely in the interests of the participants and beneficiaries of the plan. Additionally, the fact that a transaction is the subject of an exemption does not affect the requirements of Code section 401(a), including that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) In accordance with ERISA section 408(a) and Code section 4975(c)(2), and based on the entire record, the Department finds that this exemption is administratively feasible, in the interests of Plans, their participants and beneficiaries, and IRA owners, and protective of the rights of participants and beneficiaries of the Plan and IRA owners;

(3) The amended exemption is applicable to a particular transaction only if the transaction satisfies the conditions specified in the exemption; and

(4) The amended exemption is supplemental to, and not in derogation of, any other provisions of ERISA and the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

The Department is granting the following amendment on its own motion, pursuant to its authority under ERISA section 408(a) and Code section 4975(c)(2) and in accordance with procedures set forth in 29 CFR part 2570, subpart B (76 FR 66637 (October 27, 2011)).[42]

Amended Exemption

Section I. Covered Transactions

(a) Provided the conditions of Section II and IV are satisfied, the restrictions of ERISA sections 406(a)(1)(A) through (D), 406(b)(1) and 406(b)(2), and the taxes imposed by Internal Revenue Code (Code) section 4975(a) and (b), by reason of section 4975(c)(1)(A) through (E), shall not apply to a Qualified Termination Administrator (as defined in paragraph (a)(1) or (a)(2) of Section V and referred to as a QTA) using its authority in connection with the termination of an abandoned individual account plan pursuant to the Department's regulation at 29 CFR 2578.1, relating to the Termination of Abandoned Individual Account Plans (the QTA Regulation)[43] to:

(1) Select itself or an affiliate to provide services to the plan;

(2) Receive fees for the services performed as a QTA;

(3) Pay itself fees for services provided to the plan before the deemed termination of the plan; and

(4) Pay fees to the Designating Bankruptcy Trustee for services provided to the plan; and

(b) Provided that the conditions set forth in Sections III and IV of this exemption are satisfied, the restrictions of ERISA sections 406(a)(1)(A) through (D), 406(b)(1) and 406(b)(2), and the taxes imposed by Code section 4975(a) and (b), by reason of Code section 4975(c)(1)(A) through (E), shall not apply to a QTA (as defined in paragraph (a)(1) or (a)(2)(ii) of Section V) using its authority in connection with the termination of an abandoned individual account plan pursuant to the QTA Regulation to:

(1) Designate itself or an affiliate as: (i) provider of an Individual Retirement Plan; (ii) provider, in the case of a distribution on behalf of a designated beneficiary (as defined by Code section 401(a)(9)(E)) who is not the surviving spouse of the deceased participant, of an inherited Individual Retirement Plan (within the meaning of Code section 402(c)(11)) established to receive the distribution on behalf of the non-spouse beneficiary under the circumstances described in paragraph (d)(1)(ii) of the Safe Harbor Regulation for Terminated Plans (29 CFR 2550.404a-3) (the Safe Harbor Regulation); or (iii) provider of an interest bearing, federally insured bank or savings association account maintained in the name of the participant or beneficiary, in the case of a distribution described in paragraph (d)(1)(iii) of the Safe Harbor Regulation, for the distribution of the account balance of the participant or beneficiary of the abandoned individual account plan who does not provide direction as to the disposition of such assets;

(2) Make the initial investment of the account balance of the participant or beneficiary in the QTA's or its affiliate's proprietary investment product;

(3) Receive fees in connection with the establishment or maintenance of the Individual Retirement Plan or other account; and

(4) Pay itself or an affiliate investment fees as a result of the investment of the Individual Retirement Plan or other account assets in the QTA's or its affiliate's proprietary investment product.

Section II. Conditions for Provision of Covered Termination Services and Receipt of Fees

(a) *QTA Regulation.* The requirements of the QTA Regulation are met. The QTA provides, in a timely manner, any other reasonably available information

[42] Reorganization Plan No. 4 of 1978 (5 U.S.C. App. 1 (2018)) generally transferred the authority of the Secretary of the Treasury to grant administrative exemptions under Code section 4975 to the Secretary of Labor. Procedures Governing the Filing and Processing of Prohibited Transaction Exemption Applications were amended effective April 8, 2024 (29 CFR part 2570, subpart B (89 FR 4662 (January 24, 2024)).

[43] The Department intends that this exemption will cover transactions related to the interim final regulations published in this edition of the **Federal Register** as well as any subsequent final regulations published thereafter. The Department will consider amending this exemption if changes are made to the final regulation that impact the relief available under this exemption.

requested by the Department regarding the proposed termination.

(b) *Fees and expenses.* Fees and expenses paid to the QTA and its affiliate, and any Designating Bankruptcy Trustee, in connection with the termination of the plan and the distribution of benefits comply with paragraphs (d)(2)(v)(B)(2)(i) and (ii) of the QTA Regulation or paragraph (j)(7)(iv) of the QTA Regulation, as applicable;

(c) *Fees for services before the deemed termination of the plan.* In the case of a transaction described in Section I(a)(3):

(1) Such services: (i) were performed in good faith pursuant to the terms of a written agreement executed before the service provider became a QTA; or (ii) were performed pursuant to the QTA Regulation; and

(2) The QTA, in the notice of plan abandonment and intent to serve as qualified termination administrator described in paragraph (c)(3) of the QTA Regulation or in the case of a QTA described in Section V(a)(2)(i), the notice of intent to serve as qualified termination administrator described in paragraph (j)(6) of the QTA Regulation: (i) represents under penalty of perjury that such services were actually performed and/or will be performed (in the case of services provided after the notice but before deemed termination); and (ii) in the case of Section II(c)(1)(i) above, provides the Department with a copy of the executed contract between the QTA and a plan fiduciary or the plan sponsor that authorized such services.

(d) *Paying the Designating Bankruptcy Trustee.* In the case of a transaction described in Section I(a)(4):

(1) Such services were performed by the Designating Bankruptcy Trustee pursuant to the QTA Regulation; and

(2) The Designating Bankruptcy Trustee represents under penalty of perjury that such services were actually performed and/or will actually be performed and provides the QTA with such representation for the QTA to provide to the Department in the notice of intent to serve as qualified termination administrator described in paragraph (j)(6) of the QTA Regulation.

Section III. Conditions for Covered Distribution Transactions

(a) *QTA Regulation.* The conditions of the QTA Regulation (29 CFR 2578.1) are met.

(b) *Notice to participants and beneficiaries.* In connection with the notice to participants and beneficiaries described in the QTA Regulation, a statement is provided explaining that:

(1) If the participant or beneficiary fails to make an election within the 30-day period referenced in the QTA Regulation, the QTA will directly distribute the account balance to an Individual Retirement Plan or other account offered by the QTA or its affiliate;

(2) The proceeds of the distribution may be invested in the QTA's (or affiliate's) own proprietary investment product, which is designed to preserve principal and provide a reasonable rate of return and liquidity.

(c) *Exclusive benefit.* The Individual Retirement Plan or other account is established and maintained for the exclusive benefit of the Individual Retirement Plan account holder or other account holder or their beneficiaries.

(d) *Account terms, fees, and expenses.* The terms of the Individual Retirement Plan or other account, including the fees and expenses for establishing and maintaining the Individual Retirement Plan or other account, are no less favorable than those available to comparable Individual Retirement Plans or other accounts established for reasons other than the receipt of a distribution described in the QTA Regulation.

(e) *Eligible Investment Product.* Except in the case of a QTA providing a bank or savings account pursuant to Section I(b)(1)(iii) of the exemption, the distribution proceeds are invested in an Eligible Investment Product(s), as defined in Section V(c) of this class exemption.

(f) *Investment performance.* The rate of return or the investment performance of the Individual Retirement Plan or other account is no less favorable than the rate of return or investment performance of an identical investment(s) that could have been made at the same time by comparable Individual Retirement Plans or other accounts established for reasons other than the receipt of a distribution described in the QTA Regulation.

(g) *No sales commissions.* The Individual Retirement Plan or other account does not pay a sales commission in connection with the acquisition of an Eligible Investment Product.

(h) *Transferring account.* The Individual Retirement Plan account holder or other account holder must be able to transfer their account balance to a different investment offered by the QTA or its affiliate, or to a different financial institution not related to the QTA or its affiliate, within a reasonable period of time after their request and without penalty to the principal amount of the investment.

(i) *Fees and expenses.* (1) Fees and expenses attendant to the Individual Retirement Plan or other account, including the investment of the assets of such plan or account, (*e.g.,* establishment charges, maintenance fees, investment expenses, termination costs, and surrender charges) shall not exceed the fees and expenses charged by the QTA for comparable Individual Retirement Plans or other accounts established for reasons other than the receipt of a distribution made pursuant to the QTA Regulation;

(2) Fees and expenses attendant to the Individual Retirement Plan or other account, with the exception of establishment charges, may be charged only against the income earned by the Individual Retirement Plan or other account; and

(3) Fees and expenses attendant to the Individual Retirement Plan or other account are not in excess of reasonable compensation within the meaning of Code section 4975(d)(2).

Section IV. Recordkeeping

(a) The QTA maintains or causes to be maintained, for a period of six (6) years from the date the QTA provides notice to the Department of its intent to serve as the QTA described in the QTA Regulation, the records necessary to enable the persons described in paragraph (b) of this Section to determine whether the applicable conditions of this exemption have been met. Such records must be readily available to assure accessibility by the persons identified in paragraph (b) of this Section.

(b) Notwithstanding any provisions of ERISA section 504(a)(2) and (b), the records referred to in paragraph (a) of this section are unconditionally available at their customary location for examination during normal business hours by—

(1) Any duly authorized employee or representative of the Department of Labor or the Internal Revenue Service; and

(2) Any account holder of an Individual Retirement Plan or other account established pursuant to this exemption, or any duly authorized representative of such account holder.

(c) A prohibited transaction will not be considered to have occurred if due to circumstances beyond the control of the QTA, the records necessary to enable the persons described in paragraph (b) to determine whether the conditions of the exemption have been met are lost or destroyed, and no party in interest other than the QTA shall be subject to the civil penalty that may be assessed under ERISA section 502(i) or to the taxes

imposed by Code sections 4975(a) and (b), the records are not maintained or are not available for examination as required by paragraph (b).

(3) None of the persons described in paragraph (b)(2) of this Section shall be authorized to examine the trade secrets of the QTA or its affiliates or commercial or financial information that is privileged or confidential.

Section V. Definitions

(a) A termination administrator is *qualified* and considered a ''*QTA*'' for purposes of this exemption only if:

(1)(i) It is eligible to serve as a trustee or issuer of an individual retirement plan, within the meaning of Code section 7701(a)(37), and (ii) it holds assets of the plan that is found abandoned; or

(2)(i) It is a bankruptcy trustee in a liquidation proceeding under chapter 7 of title 11 of the United States Code with responsibility under 11 U.S.C. 704(a)(11) to administer one or more individual account plans sponsored by the entity that is the subject of the proceeding, who elects to be a QTA under 29 CFR 2578.1(j)(6); (ii) it is an ''*eligible designee*,'' as defined in 29 CFR 2578.1(j)(4)(i); or (iii) it is an ''*eligible designee*'' as defined in 29 CFR 2578.1(j)(4)(ii).

If a bankruptcy trustee designates an eligible designee, then it shall not be considered a QTA with respect to the relief provided in this exemption.

(b) The term ''*Individual Retirement Plan*'' means an individual retirement plan described in Code section 7701(a)(37). For purposes of Section III of this exemption, the term ''Individual Retirement Plan'' shall also include an inherited individual retirement plan (within the meaning of Code section 402(c)(11)) established to receive a distribution on behalf of a non-spouse beneficiary. Notwithstanding the foregoing, the term ''*Individual Retirement Plan*'' shall not include an employee benefit plan covered by Title I of ERISA.

(c) The term ''*Eligible Investment Product*'' means an investment product designed to preserve principal and provide a reasonable rate of return, whether or not such return is guaranteed, consistent with liquidity. For this purpose, the product must be offered by a Regulated Financial Institution as defined in paragraph (d) of this Section and shall seek to maintain, over the term of the investment, the dollar value that is equal to the amount invested in the product by the Individual Retirement Plan or other account. Such term includes money market funds maintained by registered investment companies, and interest-bearing savings accounts and certificates of deposit of a bank or similar financial institution. In addition, the term includes ''stable value products'' issued by a financial institution that are fully benefit-responsive to the Individual Retirement Plan account holder or other account holder, *i.e.,* that provide a liquidity guarantee by a financially responsible third party of principal and previously accrued interest for liquidations or transfers initiated by the Individual Retirement Plan account holder or other account holder exercising their right to withdraw or transfer funds under the terms of an arrangement that does not include substantial restrictions to the account holder's access to the Individual Retirement Plan or other account's assets.

(d) The term ''*Regulated Financial Institution*'' means an entity that: (i) is subject to state or federal regulation, and (ii) is a bank or savings association, the deposits of which are insured by the Federal Deposit Insurance Corporation; a credit union, the member accounts of which are insured within the meaning of section 101(7) of the Federal Credit Union Act; an insurance company, the products of which are protected by state guaranty associations; or an investment company registered under the Investment Company Act of 1940.

(e) An ''*Affiliate*'' of a person includes:

(1) Any person directly or indirectly controlling, controlled by, or under common control with, the person; or

(2) Any officer, director, partner or employee of the person.

(f) The terms ''*controlling*, controlled by, or under common control'' means the power to exercise a controlling influence over the management or policies of a person other than an individual.

(g) The term ''*Individual Account Plan*'' means an individual account plan as that term is defined in ERISA section 3(34).

(h) The term ''*Designating Bankruptcy Trustee*'' means a bankruptcy trustee in a liquidation proceeding under chapter 7 of title 11 of the United States Code with responsibility under 11 U.S.C. 704(a)(11) to administer one or more individual account plans sponsored by the entity that is the subject of the proceeding, that provides services to the plan but is not the QTA because of the appointment of an eligible designee.

Signed at Washington, DC, on April 22, 2024.

Lisa M. Gomez,

Assistant Secretary, Employee Benefits Security Administration, U.S. Department of Labor.

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Part IV

Office of Government Ethics

5 CFR Part 2635
Modernization Updates to Standards of Ethical Conduct for Employees of the Executive Branch; Final Rule

OFFICE OF GOVERNMENT ETHICS

5 CFR Part 2635

RIN 3209–AA43

Modernization Updates to Standards of Ethical Conduct for Employees of the Executive Branch

AGENCY: Office of Government Ethics.

ACTION: Final rule.

SUMMARY: The U.S. Office of Government Ethics (OGE) is issuing this final rule updating the Standards of Ethical Conduct for Employees of the Executive Branch (Standards). The final rule updates the Standards based on OGE's experience gained from application of the regulation since its inception. The final rule also incorporates past interpretive guidance, adds and updates regulatory examples, improves clarity, updates citations, and makes technical corrections.

DATES: This final rule is effective August 15, 2024.

FOR FURTHER INFORMATION CONTACT: Kimberly L. Sikora Panza, Senior Associate Counsel, or Christie Chung, Assistant Counsel, U.S. Office of Government Ethics, 250 E Street SW, Suite 750, Washington, DC 20024–3249; Telephone: 202–482–9300; TTY: 800–877–8339; FAX: 202–482–9237.

SUPPLEMENTARY INFORMATION:

I. Rulemaking History

Pursuant to a provision of the Ethics in Government Act of 1978, 5 U.S.C. 13122, the Director of the U.S. Office of Government Ethics (OGE) is responsible for periodically reviewing, evaluating, and updating the rules and regulations that pertain to ethics in the executive branch. On February 21, 2023 (88 FR 10774), OGE published for public comment a proposed rule setting forth various modernization updates to the Standards of Ethical Conduct for Employees of the Executive Branch (Standards), which serve as the primary regulatory guidance on the standards of ethical conduct for officers and employees of the executive branch of the Federal Government (Government). Prior to publishing the proposed rule, OGE consulted with the Department of Justice and the Office of Personnel Management pursuant to section 201(a) of Executive Order 12674, as modified by Executive Order 12731, and the authorities contained in 5 U.S.C. chapter 131, subchapter II. Additionally, OGE solicited and considered the views of executive branch agency ethics officials. OGE's proposed updates pertained only to subparts A through I of the Standards; separate from the present rulemaking, OGE engaged in a comprehensive rulemaking that added to the Standards new subpart J, which relates to the creation and operation of legal expense funds, and the acceptance of pro bono legal services for certain legal matters. See 88 FR 33799 (May 25, 2023).

The proposed rule provided for a 60-day comment period, which ended on April 24, 2023. During this period, OGE received nineteen responsive comment submissions regarding the proposed rule: fourteen from the public and five from Federal agencies. OGE also received two comment submissions from the public that do not relate to the proposed rule and address unrelated matters. After carefully considering all comments and making appropriate modifications, and for the reasons set forth below and in the preamble to the proposed rule at *https://www.govinfo.gov/content/pkg/FR-2023-02-21/pdf/2023-02440.pdf,* OGE is publishing this final rule.

II. Discussion of Comments and Changes to Proposed Rule

The twenty-one comments that OGE received during the comment period are publicly accessible on OGE's website at this address: *https://www.oge.gov/web/OGE.nsf/All+docs+By+Cat/08C3B547690B7675852589AA00556758.* OGE has reviewed and considered all comments submitted by each commenter. OGE is not addressing the two comments that pertain to matters unrelated to the rulemaking. The following discussion addresses all other comments in the context of the specific subparts or sections to which they relate.

A. General Provisions (Subpart A)

OGE received nine comments from individuals who expressed concerns about the proposed revisions to §§ 2635.101(b)(13) and 2635.106. In §§ 2635.101(b)(13) and 2635.106, OGE proposed to add the words ''(including pregnancy, gender identity, and sexual orientation)'' after ''sex'' to reflect protected characteristics identified by the Equal Employment Opportunity Commission (EEOC) as covered by Federal employment discrimination laws. Towards this same end, OGE also proposed adding ''genetic information'' in these two sections and updating the word ''handicap'' to ''disability.'' These commenters specifically criticized the inclusion of ''gender identity'' and ''sexual orientation'' in §§ 2635.101(b)(13) and 2635.106; no commenter referenced or objected to the other updates to these provisions relating to pregnancy, genetic information, or disability. Commenters perceived that the inclusion of ''gender identity'' and ''sexual orientation'' would result in an expansion of civil rights, and objected to the revisions either categorically or without observance of appropriate protections for religious organizations and religious conscience.

The revisions to §§ 2635.101(b)(13) and 2635.106 do not effectuate any expansion of, or other change to, civil rights laws. Significantly, OGE does not have the authority to promulgate regulations expounding on the scope of categories protected by equal employment laws and regulations, or other civil rights laws and regulations. The updated language merely modernizes the regulatory text to include characteristics that the EEOC already recognizes as protected under the laws enforced by the Commission. *See, e.g., Employees & Applicants,* U.S. Equal Emp. Opportunity Comm'n, *https://www.eeoc.gov/employees* (last visited May 17, 2023). It is both necessary and appropriate that provisions in the Standards that refer to ''laws and regulations that provide equal opportunity'' list the characteristics protected by Federal laws prohibiting employment discrimination and enforced by the EEOC.

Additionally, OGE received one comment from an individual who expressed concern that the addition of ''gender identity'' and ''sexual orientation'' infringes on executive branch employees' First Amendment and other constitutional rights. As noted above, these revisions are merely technical updates referencing types of discrimination already recognized by the EEOC. Acknowledgement of the fact that sex-based discrimination includes gender identity and sexual orientation in §§ 2635.101(b)(13) and 2635.106 neither results in any change to existent equal opportunity laws or regulations, nor impacts the interaction between such laws and the constitutional rights of employees.

For the above reasons and for the reasons stated in the preamble to the proposed rule, OGE therefore is adopting the proposed updates to subpart A without further revisions.

B. Gifts From Outside Sources (Subpart B)

Subpart B Examples

OGE received four suggestions regarding additional examples or clarifications that could be made in subpart B. Specifically, one agency

commenter suggested that OGE add an example of a ''non-traditional'' prohibited source, such as an entity that enters into a cooperative research and development agreement with a Federal agency, as well as an example involving a lottery ticket as a gift; the same agency suggested that OGE add an example to § 2635.204(d) involving a Department of Defense or other Federal school; and a member of the public suggested that OGE clarify gift acceptance limits and issues relating to entities like the Kennedy Center where events might be hosted by a corporate donor.

The examples requested by these commenters involve illustration of fairly specific situations. It would not be feasible for OGE to provide examples addressing application of the regulation in all of the scenarios that may give rise to subpart B considerations. In light of the extensive revisions made to subpart B in 2016, which included modernization changes and examples, and OGE's determination that the current rule provides appropriate guidance, OGE declines these suggestions.

Gift Exclusion and Exception for ''Opportunities and Benefits''

One individual commenter requested that OGE reconcile the difference between the opportunities and benefits excluded from the definition of ''gift'' in § 2635.203(b)(4) and the opportunities and benefits excepted from the gift prohibitions by § 2635.204(c)(2). Specifically, the commenter noted that the opportunities and benefits excluded from the ''gift'' definition by § 2635.203(b)(4) include ''favorable rates and commercial discounts,'' while the opportunities and benefits excepted from the subpart B gift prohibitions by § 2635.204(c)(2) include ''favorable rates, commercial discounts, and free attendance or participation.'' The ''free attendance or participation'' language that distinguishes these two provisions was added to § 2635.204(c)(2) when OGE substantially revised subpart B in 2016. *See* 81 FR 81641 (Nov. 18, 2016).

OGE notes that the ''opportunities and benefits'' listed in the § 2635.203(b)(4) gift exclusion are preceded by the word ''including,'' indicating that the list is not intended to be exhaustive. As such, one could consider free attendance or participation under the gift exclusion, if the appropriate facts presented themselves. However, to clear up any confusion, OGE will add the words ''free attendance or participation'' to § 2635.203(b)(4) to harmonize the language in §§ 2635.203(b)(4) and 2635.204(c)(2).

Free Attendance Gift Exclusion

Section 2635.203(b)(8) excludes from the definition of ''gift'' free attendance to an event provided by the sponsor of the event to certain individuals, including an employee who is assigned to present information on behalf of the agency at the event (on any day when the employee is presenting), and ''[a]n employee whose presence on any day of the event is deemed to be essential by the agency to the presenting employee's participation in the event,'' if the employee is accompanying the presenting employee. One agency opined that it is unclear whether multiple personnel supporting a presenting employee may accept free attendance pursuant to this exclusion. Specifically, the commenter requested that ''an employee'' in the above-quoted language in § 2635.203(b)(8)(ii) be changed to ''any employee'' to clarify that multiple supporting personnel may accept free attendance under this exclusion.

OGE notes that it has previously issued guidance making clear that § 2635.203(b)(8)(ii) can be applied to multiple agency personnel. *See* OGE DAEOgram DO–10–003, at 2 (Feb. 18, 2010) (''The number and types of personnel necessary, if any, to the speaker's participation will vary depending upon who the speaker is and the nature of the event.''). Nonetheless, to further address the commenter's concern, OGE is updating example 2 to paragraph (b)(8) to reflect that guidance and eliminate any doubt that multiple supporting personnel may accept free attendance under this exclusion. Specifically, OGE is changing ''another employee'' to ''other employees'' and ''accompanying employee'' to ''accompanying employees'' in the example.

De Minimis Gift Exception

Three commenters—two individuals and one agency—recommended that OGE increase the monetary thresholds for the *de minimis* gift exception at § 2635.204(a), noting the effects of inflation in the intervening years since the exception was first adopted. Two other commenters made a similar suggestion in 2016 as part of OGE's comprehensive rulemaking revising portions of subpart B.

After carefully considering this recommendation in 2016, OGE noted its concern that ''raising the *de minimis* would encourage employees to accept, and private citizens to give, more expensive and more frequent gifts than employees are currently able to accept.'' 81 FR 81641, 81645 (Nov. 18, 2016). Although OGE acknowledged at that time—and continues to acknowledge—the effect of inflation on the relative value of the *de minimis* threshold, OGE continues to believe that $20 is a workable amount that serves the narrow purpose of the exception, which is to permit only the infrequent acceptance of inexpensive and innocuous gifts. *Id.; see also* 57 FR 35006, 35016 (Aug. 7, 1992). It also continues to be the fact that ''no compelling argument has been made to support a conclusion that raising the cap on the blanket *de minimis* exception, in order to allow employees to accept more expensive and more frequent gifts, would strengthen the integrity of the executive branch's operations.'' 81 FR 81645.

Independent of these substantive reasons, OGE also declines to adopt the suggestion to increase the *de minimis* threshold in this particular rulemaking, the primary focus of which is on technical, non-substantive updates. OGE does not think it would be appropriate to adjust the § 2635.204(a) dollar value in this final rule without having announced in the proposed rule that it was contemplating such an increase, thereby providing the public an opportunity to reflect on such a proposal and share their input regarding the same.

Widely Attended Gatherings Exception

To improve readability, OGE is making a technical amendment to the structure of § 2635.204(g)(2), which defines when a gathering is widely attended for purposes of the widely attended gathering (WAG) exception. Specifically, OGE is organizing the components of the WAG definition at § 2635.204(g)(2) into new separate paragraphs (g)(2)(i) through (iii). This update involves no substantive changes to the WAG exception.

In response to the proposed rule, one agency recommended removing the requirement in the WAG exception in § 2635.204(g) that an employee attend the event on their own time in their personal capacity rather than in their official capacity. Section 2635.204(g) provides that an employee could attend a qualifying event either on their own time or, if authorized by their agency, on excused absence pursuant to applicable guidelines for granting such absence, or otherwise without charge to the employee's leave account. The commenter questioned the rationale for this requirement that the employee attend on their own time, noting that an agency determination that attendance is in the agency's interest would suggest the event is related to the employee's official duties.

OGE notes that the requirement that the employee attend in their personal capacity is based on appropriations considerations that OGE documented in the preamble to the final rule for 5 CFR part 2635. *See* 57 FR 35006, 35019–20 (Aug. 7, 1992). The 1992 preamble explains that the WAG exception was designed to allow agencies that do not have agency gift acceptance authority to permit their employees to accept a gift of free attendance at events in which the agency has an interest in the employee attending. However, due to appropriations requirements, in order for the gift to be accepted by an employee rather than by the agency, the employee must attend the event in their personal capacity ''off the clock.'' Specifically, this requirement ''is imposed of necessity to ensure that the gift is made to the employee rather than to the agency and, thus, that it does not improperly augment agency appropriations available for payment of expenses of attendance at training, meetings or similar events.'' *Id.* at 35019. For these reasons, OGE declines to follow the agency's recommendation.

C. Gifts Between Employees (Subpart C)

Gifts to Superiors

One individual commented that the proposed new language in § 2635.302(a)(1), which clarifies that ''an official superior may not knowingly accept'' an improper gift from a subordinate, is inconsistent with the controlling statutory authority at 5 U.S.C. 7351. The commenter also suggested that the knowledge element in this provision is unclear.

As discussed in the preamble to the proposed rule, the premise that official superiors have a responsibility to not knowingly accept improper gifts from a subordinate is logically consistent with and complements the restrictions articulated in 5 U.S.C. 7351 governing gift giving from a subordinate to a superior. The proposed changes to § 2635.302(a)(1) appropriately emphasize that superiors should not knowingly accept gifts that are improper for employees to give.

Regarding the knowledge element relating to a superior's acceptance of a gift, it is included in recognition of the fact that the regulation covers gifts given ''indirectly'' by an employee—*e.g.,* ones given by an employee's parent, sibling, spouse, child, or dependent relative with the employee's knowledge and acquiescence. *See* § 2635.303(b)(1). Section 2635.302(a) is structured in such a way that knowledge is required on the part of both the giver and receiver for indirect gifts. For example, an employee will not be in violation of the rule if their sibling gives a gift to the employee's superior without the employee's knowledge and acquiescence. Similarly, a superior will not be in violation of the rule if they accept a gift that unbeknownst to them was given by the sibling of an employee with the employee's knowledge and acquiescence.

For the reasons explained in the preamble to the proposed rule, OGE declines the commenter's suggestions, and will adopt the revisions to § 2635.302(a)(1) as set forth in the proposed rule.

Gifts From Employees Receiving Less Pay

One individual commenter requested clarification regarding the meaning of ''less pay'' in § 2635.302(b) and suggested that the rule be amended to specify ''base pay.'' OGE is unable to adopt this change. The language in § 2635.302(b), referring to ''employees receiving less pay'' incorporates the language of the underlying statute. *See* 5 U.S.C. 7351 (referring to ''an employee receiving less pay''). Given this statutory basis, OGE is constrained in its ability to revise the regulation to specify ''base pay'' or ''rate of basic pay.''

Another individual commenter opposed the new language OGE proposed to add to § 2635.302(b)(2), which clarifies that the restriction on accepting a gift from an employee receiving less pay does not apply when the employee giving the gift is the official superior of the employee receiving the gift. The commenter expressed concern that this rule could provide for unequal treatment among the higher paid employees who are now allowed to receive gifts from their superiors, although the commenter also recognized that gifts from superiors to subordinates are not generally restricted by subpart C.

OGE disagrees with the commenter that the updated language is ripe for ''favoritism and impropriety.'' As a threshold matter, OGE notes that in the status quo, subpart C does not restrict most gifts from superiors to their employees because superiors do not typically receive less pay than their employees. This structure does not seem to have elicited much concern among ethics officials. Furthermore, as OGE noted in the proposed rule, ''OGE does not believe that 5 U.S.C. 7351, the statute underlying the restriction articulated in § 2635.302(b), either contemplated or intended that subordinate employees would be restricted from accepting a gift from an official superior who, because of the nature of modern compensation systems, receives less pay.'' 88 FR 10774, 10775 (Feb. 21, 2023). Accordingly, this updated language that permits all employees to receive gifts from their superiors in the same manner is necessary to modernize and equalize the rule given the situations in the current Federal pay system in which a subordinate may earn more than their official superior. However, it does not encourage the provision of such gifts in an unfair or inequitable manner.

De Minimis Gift Exception

Similar to the related suggestions regarding the subpart B *de minimis* exception, two agency commenters recommended that OGE increase the monetary threshold in the gift exception at § 2635.304(a). As is the case with the *de minimis* exception in § 2635.204(a), OGE believes that the current value of the *de minimis* exception in subpart C should remain unchanged. As OGE noted when issuing the Standards, while it is ''appropriate to permit modest exchanges of gifts between coworkers,'' it is important to remain mindful of ''subtle pressures to give gifts to superiors'' in an environment ''where superiors and subordinates interact daily and where subordinates compete for advancement.'' 57 FR 35006, 35022 (Aug. 7, 1992). Notwithstanding inflation, OGE believes that the $10 amount remains adequate to permit an exchange of a modest token between employees and is ''low enough generally to discourage employees from purchasing gifts for their superiors.'' *Id.* OGE further echoes its concern noted above about adjusting a *de minimis* value in this final rule when the public was not apprised of such a potential change or given the opportunity to comment on it.

Special Infrequent Occasions Exception

One agency commenter suggested that OGE add a new example to the exception for special, infrequently occurring occasions to illustrate that a superior's promotion is not an occasion of personal significance. OGE declines to adopt this suggestion. Example 3 to the exception for voluntary contributions in § 2635.304(c) sufficiently illustrates that a superior's promotion within the supervisory chain is not an appropriate time for subordinates to take up a collection for a gift to that official superior because the occasion does not ''mark the termination of the subordinate-official superior relationship, nor [is it an] event[ ] of personal significance within the meaning of [§ 2635.304(b)].''

An individual commenter suggested that OGE consider adding ''divorce'' to the non-exhaustive list of special, infrequent occasions covered by the exception at § 2635.304(b)(1), and also suggested that OGE could add further detail in the regulation regarding the application of this exception in other contexts, such as traditional religious or cultural rites of passage.

OGE notes that the statute authorizing OGE to issue regulations exempting certain gifts contemplates that OGE may exempt gifts in circumstances ''in which gifts are traditionally given or exchanged.'' 5 U.S.C. 7351(c). The list of special, infrequent occasions provided in the regulation is not exhaustive, as it is preceded by the phrase ''such as.'' OGE does not endeavor to attempt to list all occasions that may be covered in the regulation, nor does it believe it would be prudent or practicable to articulate every such occasion. The language of the exception makes clear that the exception allows for gifts that are ''infrequently occurring occasions of personal significance,'' and this language should be applied when considering occasions not included in the non-exhaustive list.

Regarding this same exception, a different individual commenter agreed that adding ''bereavement'' to § 2635.304(b) is a beneficial change; the individual suggested, however, that there are issues in practice with OGE's inclusion of this term without limitation. Specifically, the commenter recommended that OGE establish ''limitations as to which family members the exception applies.'' OGE declines to adopt language qualifying which bereavements constitute an infrequently occurring occasion of personal significance, believing that it is neither appropriate nor wise to make a categorical determination about which losses justify expressions of sympathy. OGE notes that a gift in recognition of bereavement must still be ''appropriate to the occasion,'' which is a sufficient limiting factor that appropriately curtails gift giving and acceptance in the bereavement context and addresses any potential for misuse of the narrow exception at § 2635.304(b).

This same commenter recommended that OGE add birthdays ending in zero to the non-exhaustive list of special, infrequent occasions covered by § 2635.304(b)(1). Drawing parallels between birthdays ending in zero and occasions enumerated in the regulation, the individual commented that exclusion of milestone birthdays is arbitrary. OGE believes that it would be inappropriate to except gifts in connection with birthdays, which includes milestone birthdays, from the general rules governing gifts between employees, and thus did not revise the regulation to indicate otherwise. As noted in the preamble accompanying the proposed rule, OGE does not consider milestone birthdays to be infrequently occurring occasions of the sort warranting exception under § 2635.304(b). Of course, it may be possible to give a gift in recognition of any birthday under another exception, such as the exception for gifts with a value of $10 or less and the exception for food and refreshments shared in the office among several employees. *See* § 2635.304(a)(1) and (2).

Exception for Voluntary Contributions of Nominal Amounts

One individual commenter suggested that OGE define the term ''nominal'' as it is used in the exception at § 2635.304(c) for ''voluntary contributions of nominal amounts from fellow employees for an appropriate gift to an official superior.'' OGE appreciates this suggestion, but has not made a change to the regulation. What constitutes a ''nominal'' amount is necessarily context-specific, for example, depending on whether the contribution is for items like food and refreshments, or for a gift in recognition of a special, infrequent occasion. In response to a similar comment when first issuing the Standards, OGE explained that it chose to not impose a specific dollar limit, even though collections for gifts generally involve individual contributions less than five dollars. In doing so, OGE noted that ''[w]here contributions meet the regulatory requirement that they be entirely voluntary, higher amounts may appropriately be contributed in some cases, as when several senior members of an office provide an additional contribution to subsidize a collection that has come up short of sufficient funds to purchase a desired gift.'' 57 FR 35006, 35023 (Aug. 7, 1992). The regulation makes clear that the contributions must be for ''an appropriate gift,'' which OGE believes provides a suitable, non-monetary limit on the use of this exception.

Disposition of Prohibited Gifts

One agency commenter suggested that OGE add a section in this subpart that addresses what an employee should do if they inadvertently accept a gift that is not permissible under this subpart. In response to agency inquiries regarding the disposition of gifts prohibited by subpart C, OGE has advised that agencies are free to look to the subpart B disposition provisions for guidance regarding how to handle such gifts. To provide greater clarity to employees and ethics officials, OGE will add a new § 2635.305 to subpart C that is consistent with that guidance.

D. Conflicting Financial Interests (Subpart D)

Analyzing Imputed Interests and Multi-Entity Organizations

One agency commenter requested that OGE add an example in § 2635.402 illustrating the application of 18 U.S.C. 208 where an employee has an imputed financial interest by virtue of their outside employment or position with an organization, and there is a particular matter that could affect one of the entity's campuses, or a parent, affiliate, or subsidiary organization. OGE declines to add such an example. As a threshold matter, OGE notes that the Standards already provide clear guidance regarding how imputed relationships are analyzed. Specifically, § 2635.402(b)(2) explains that ''[f]or purposes of 18 U.S.C. 208(a) and this subpart, the financial interests of [certain imputed persons, including an organization or entity with which an employee serves as officer, director, trustee, general partner or employee] will require the recusal of an employee *to the same extent as if they were the employee's own interests.*'' (Emphasis added.) Regarding related entities such as parents, subsidiaries, affiliates, etc., the Standards generally acknowledge the potential conflicts that may arise with respect to the same. *See* note 2 to § 2635.402(b)(1) (recognizing that a party matter may have a direct and predictable effect on an employee's financial interest in an affiliate, parent, or subsidiary of that party). Ultimately, however, OGE is wary of potential misinterpretation and misapplication were it to include an example of the sort requested by this commenter, and believes that a Legal Advisory is a more suitable means through which to provide guidance on the appropriate analysis.

Example 1 to § 2635.403(b)

One individual commenter questioned OGE's proposed inclusion of a dollar amount in example 1 to § 2635.403(b) and suggested that the value should be removed because it ''is not . . . important for the rule's applicability.'' OGE intends to retain the dollar amount in this example. As explained in the preamble to the proposed rule, OGE proposed adding a specific dollar figure to the amount of stock owned by the employee in the example ''to make clear that the *de*

minimis regulatory exemption in 5 CFR 2640.202 does not apply in this scenario.'' Accordingly, as noted in the example, the agency could determine that ''the employee could not, by virtue of 18 U.S.C. 208(a), perform these significant duties of the position while retaining stock in the company.''

Definition of Financial Interest

The same individual commenter questioned OGE's proposed update to the definition of ''financial interest'' in 5 CFR 2635.403(c)(1), which replaces the word ''dependent child'' with ''minor child,'' and expressed a preference for retaining ''dependent child.'' As stated in the language of § 2635.401 that this rulemaking will adopt, subpart D ''summarizes the relevant statutory restrictions [of 18 U.S.C. 208] and some of the regulatory guidance found'' in 5 CFR part 2640, the part interpreting and implementing 18 U.S.C. 208. The updated language referencing ''minor child'' brings § 2635.403(c)(1) into alignment with the language used throughout subpart D, and reflects the terminology of the statute proper and its implementing regulation. Therefore, OGE declines to retain the ''dependent child'' language in § 2635.403(c)(1) or otherwise integrate the concept of ''dependent child'' in this subpart.

E. Impartiality in Performing Official Duties (Subpart E)

Subpart E Examples

OGE received one comment from an individual concerning the application of § 2635.502 to particular matters of general applicability and requesting the addition of an example illustrating that application. As proposed, reorganized § 2635.502 articulates the operation of the regulation with respect to particular matters involving specific parties in which a household member has a financial interest, and particular matters involving specific parties in which someone with whom one has a covered relationship is or represents a party. Section 2635.502(a)(3) makes clear that employees who are concerned about impartiality questions arising from circumstances other than the party matters described in the preceding sentence—which could include particular matters of general applicability—should utilize the process detailed in the regulation, including in paragraph (d), to determine whether their participation is appropriate. In 1991, OGE addressed this ''catch-all'' provision in the preamble to the proposed rulemaking for the Standards, explaining that although the section focused on specified relationships and party matters, questions about an employee's impartiality could arise from any number of interests or relationships they might have, and in connection with their participation in matters that do not necessarily involve specific parties. 56 FR 33778, 33786 (July 23, 1991). For this reason, § 2635.502 ''therefore provides that an employee should use the process set forth in that section when circumstances other than those specifically described raise questions about [their] impartiality in the performance of official duties.'' Id. Given this guidance, OGE declines to add an example illustrating the specific application of § 2635.502 to particular matters of general applicability.

For similar reasons, OGE declines to add a very fact-specific example suggested by a different individual regarding how previous litigation history between an employee and party to a matter might give rise to impartiality concerns.

Employee Work Assignments

OGE received two comments from the public expressing concern that the new note at § 2635.501 could be viewed as being in conflict with, or causing confusion regarding, regulatory language in §§ 2635.105(a) and 2638.602 regarding how supplemental agency ethics regulations require OGE's concurrence, with co-signature and publication by the agency and OGE. One commenter questioned whether the intent of the note was to indicate that agencies have unfettered authority to assign work as they see fit, and whether a manager's delegation of work based on ethics considerations would be contrary to § 2635.105 if not subject to OGE review. The second commenter asked OGE to make clear what triggers the requirement to memorialize an ethics requirement in a supplemental regulation versus merely issuing an agency policy.

As discussed in the preamble to the proposed rule, the note is not an independent source of authority; it simply reminds agency ethics officials that supervisors generally have broad discretion when assigning work to employees and that there may be a multitude of factors considered by a supervisor in doing so, including appearance or impartiality concerns that do not fit squarely within the Standards. OGE has no intention to alter the requirements relating to supplemental ethics regulations, nor could it do so in this rulemaking, as those general requirements are established by Executive order. *See* E.O. 12731, sec. 301(a) (Oct. 17, 1990). Agencies wishing to supplement the Standards with additional ethics obligations still must follow the requirements of § 2635.105, as referenced in § 2638.602, and may rely on prior OGE guidance regarding what agency ethics policies belong in a supplemental regulation. *See, e.g.,* OGE Legal Advisory LA–11–07 (Oct. 31, 2011).

Covered Relationship Stemming From Certain Familial Relations

One individual commenter stated their support for the removal of the ''dependent'' qualifier when discussing covered relationships relating to certain business activities of children, noting that ''[a] non-dependent child is more likely to have relationships that implicate impartiality concerns than dependent children, who, being dependents as defined at 26 U.S.C. 152 (*e.g.,* minors or students), are relatively unlikely to have the sorts of business relationships raising those concerns.'' An agency commenter disagreed with OGE's proposal to remove the ''dependent'' qualifier, suggesting that the financial co-dependence of parents and dependent children is more likely to raise concerns regarding impartiality.

OGE will adopt as final the change removing the ''dependent'' qualifier before ''child'' in § 2635.502(b)(1)(iii). This change appropriately reflects that there are potential impartiality concerns relating to certain business relations of a child regardless of that child's dependency, just as long-established language in § 2635.502(b)(1)(iii) acknowledges impartiality concerns relating to certain business relations of a parent, without any dependency predicate. The updated language harmonizes the treatment of parents and children for purposes of the scope of certain covered relationships because both familial relations may raise similar ethics concerns, irrespective of any financial connection or perceived financial impact. In that regard, OGE notes that nothing in subpart E contemplates that there need be a perceived impact on an employee's financial interests for there to be concerns about their impartiality, and that many of the long-established covered relationships articulated in § 2635.502(b) would not seem to involve such a perceived impact. Of course, we note that § 2635.502 does not demand a specific outcome regarding participation when an appearance concern arises; it merely requires that employees engage in the appropriate analysis under this subpart before participating. As we stated in the 1992 preamble to the final rule for the Standards, ''the importance of relevant facts must be emphasized.''

57 FR 35006, 35027 (Aug. 7, 1992). To highlight this point as applied to the revised covered relationship provision, OGE is updating new example 6 to § 2635.502(b) so that the scenario described involves the employment relationship of an adult child. This example now illustrates a situation where a covered relationship described in paragraph (b)(1)(iii) exists—a covered relationship with the employer of an employee's adult child—but the employee could justifiably conclude that a reasonable person would not be likely to question their impartiality in participating in a party matter involving the child's employer.

Covered Payments and Qualifying Programs

OGE received one comment from an agency regarding the proposed update to the definition of a ''qualifying program'' at § 2635.503(b)(2), which requires that the written program ''not treat individuals entering Government service more favorably than other individuals.'' The commenter noted that this language covers the types of commonly written policies that permit for the acceleration of benefits or lump sum payouts for individuals entering Government service, which can expedite the transition to Government service, and expressed concern that this change would cause unnecessary delays and conflicts in that transition.

OGE notes that the updated language in § 2635.503(b)(2) does not affect OGE's position that ''when the ownership of the interest has already vested[,] an employee may receive an earlier payment to remediate a conflict of interest without running afoul of either 18 U.S.C. 209 or 5 CFR 2635.503. This is because the employee is entitled to receive the payment and only the timing is being altered, not the entitlement to the payment itself.'' U.S. Off. of Gov't Ethics, Conflicts of Interest Considerations: Corporate Employment 5 (2021), *https://www.oge.gov/web/OGE.nsf/0/EC83872D932E6DCE852585B6005A1F8C/$FILE/Corporate%20Employment.pdf.* Accordingly, if an employee receives accelerated payment of an already vested equity interest, that payment still would not implicate § 2635.503.

Regarding the revisions to the definition of ''qualifying program,'' which OGE will adopt as proposed, OGE has noted an increase in written policies and programs favoring Government employees, which OGE did not anticipate when it first promulgated § 2635.503. OGE therefore intentionally updated the definition of ''qualifying program'' to exclude written plans and programs that provide favorable treatment to employees entering Government service, such as accelerated vesting of employment-related interests. This approach is consistent with how OGE has viewed unwritten practices of treating employees entering Government more favorably. Whether made pursuant to a program or a practice, a covered payment received from a former employer raises ''a legitimate concern, and thus an appearance, that the employee may not act impartially in particular matters to which the former employer is a party or represents a party.'' 56 FR 33778, 33786 (July 23, 1991). OGE does not have any indication that this modernized regulation, which is focused on an employee's recusal obligation once serving the Government, would cause unnecessary delays and conflicts during the transition into Federal service.

Inclusion of Former Clients in the Former Employer Definition

The same agency requested that OGE revise note 1 to paragraph (b)(3) in § 2635.503 to ''clarify that former clients are those for whom the individual personally provided services, and not all clients of a larger firm.'' Note 1 states that the ''former employer'' definition ''includes former clients *for whom an employee may have served* as an agent, attorney, consultant, or contractor.'' (Emphasis added.) OGE believes that the Note is clear on its face that the term ''former clients'' refers to those for whom the employee personally provided services, and thus will adopt the proposed language without amendment.

F. Seeking Other Employment (Subpart F)

Subpart F Examples

OGE received one comment from an individual requesting an additional example in subpart F to clarify whether an employee may rely on third-party information to conclude that a prospective employer has rejected the possibility of hiring the employee. Specifically, the commenter suggested an example where an employee learns from a third party that they are no longer under consideration—for example, because the position has been filled by someone else. OGE declines to make this change for several reasons. First, OGE in 2016 published substantive updates to subpart F, which included several new examples to illustrate the application of subpart F to modern job searches. This rulemaking is only proposing global technical changes throughout subpart F, which is consistent with the purpose of the modernization project. Second, OGE notes that the legitimacy of the information received from third parties is likely to vary significantly on a case-by-case basis. As such, an example involving information from a third party would be unlikely to provide helpful insight—and worse, could be misconstrued to imply that all third-party information can be relied upon in the same way. Finally, OGE believes the current structure of subpart F provides sufficient guidance to assess scenarios where the employee receives credible information that the prospective employer has rejected the possibility of employment.

Seeking Employment Definition

This same individual asserted that the definitions in subpart F do not take into consideration the possibility that an employee might seek employment by posting their interest on social media or meeting with a recruiter who will communicate with multiple, potentially unknown, companies. OGE disagrees with this commenter. As part of the 2016 updates to subpart F, OGE modernized the rule and added three new examples of seeking employment involving social media. OGE added these examples to ''clarify that the rules in this subpart apply regardless of the method the employee uses when seeking employment.'' 81 FR 8008, 8009 (Feb. 17, 2016). As further discussed in the 2016 preamble, the examples illustrate that the posting of a profile, resume, or other employment information that is not targeted to a specific person is not considered an unsolicited communication with an entity regarding possible employment; instead such a posting is akin to posting a resume on a bulletin board. Moreover, if the employee is using an agent or other intermediary when seeking employment, the definition of ''prospective employer'' is met only ''if the agent identifies the prospective employer to the employee.'' 5 CFR 2635.603(c)(1) and (2) and example 2 to paragraph (c) (discussing a scenario involving an online resume distribution service that sends resumes to recruiters). Accordingly, OGE is declining to make further updates.

This individual also suggested that OGE shorten the two-month timeframe in § 2635.603(b)(2)(ii), which provides that, in the absence of a response from a prospective employer indicating interest, an employee is no longer seeking employment—and thus no longer has a recusal requirement under subpart F—after two months have elapsed from their dispatch of an

unsolicited resume or job proposal. The commenter recommended truncating this timeframe given changes in the mechanisms through which individuals search for jobs, and potentially quicker responses from prospective employers than was the case in years past.

The provision about which this commenter is providing input was substantively unchanged by the proposed rule, which noted that OGE endeavors to make only global technical changes to subpart F that are proposed throughout the Standards. OGE does not believe that the two-month period prescribed in § 2635.603(b)(2)(ii) is an unreasonably excessive period of time in the modern job market. Even with the technologies of current day, OGE continues to view two months as a realistic period of time within which an individual may expect a response to an unsolicited resume or job proposal. Subpart F addresses lack of impartiality concerns warranting recusal from particular matters affecting the financial interests of a prospective employer with whom the employee is seeking employment. In weighing this comment against the concerns underpinning subpart F, OGE is not inclined to relax the recusal requirement in the manner suggested. Moreover, we note, as we did in 1992 when issuing the final rule establishing the Standards, ''that the two-month period establishes an outside limit. An earlier response from the recipient indicating no interest in pursuing the matter further will terminate the employee's disqualification at that time.'' 57 FR 35006, 35029 (Aug. 7, 1992). Thus, to the extent that the timeframe in ''which an applicant will hear back from a prospective employer'' is shorter, as suggested by the commenter, an employee who receives a negative response will be relieved of their subpart F recusal obligation at that point.

G. Misuse of Position (Subpart G)

Letters of Recommendation

OGE received multiple comments relating to § 2635.702(b), a section in which OGE did not propose any substantive changes. One agency commenter recommended that OGE add an additional example to § 2635.702(b) to illustrate that an employee may use their official title in connection with providing a recommendation for an individual with whom they have dealt in the course of Federal employment outside of the executive branch—for example, an individual with whom the employee worked while assigned to a Congressional office. OGE declines to adopt this suggestion, as it considers the language in § 2635.702(b) to be sufficiently clear in its broad phrasing that an employee's official title may be used in connection with a reference for an individual with whom the employee has dealt not just in connection with executive branch employment, but ''in the course of Federal employment.''

A different agency requested that the last sentence of § 2635.702(b) be updated such that employees may recommend individuals using their official title not just for Federal employment, but also for other opportunities such as Federal internships or educational programs. OGE believes that § 2635.702(b) appropriately permits recommendations for Federal employment, and declines to expand the regulatory language as suggested by the commenter to cover other Federally associated opportunities. As a point of clarification, however, OGE notes that some internships and positions associated with a Federal entity may qualify as ''Federal employment,'' *see, e.g.,* OGE Legal Advisory LA–17–09 (Aug. 14, 2017) (discussing different hiring authorities for and employment status of student interns), such that it would be permissible under § 2635.702(b) for an employee to use their official title to recommend an individual for the same.

The same agency expressed concern that example 1 to § 2635.702(b) suggests that ''it is entirely acceptable for an employee to recommend a person for Federal employment (including use of the employee's title and official letterhead) solely because the person is a personal friend.'' As a threshold matter, OGE notes it did not propose to substantively update this example in this rulemaking. Furthermore, the example is consistent with § 2635.702(b), which specifically permits an employee to use their official title to recommend individuals for Federal employment, including personal friends. As explained in the preamble to the final rule establishing the Standards, OGE believes that recommending an individual for Federal employment serves an ''official purpose'' that justifies the use of official title. *See* 57 FR 35006, 35031 (Aug. 7, 1992).

Personal Social Media and Use of Official Photographs

As discussed in the proposed rulemaking, OGE is adding a new example of an appearance of governmental sanction following § 2635.702(b), which involves the use of personal social media by an Environmental Protection Agency (EPA) employee. The example is consistent with OGE's Legal Advisory on personal social media use and illustrates the factual determination that agency ethics officials must make in evaluating whether a reference to an employee's official title or position on social media violates the Standards. *See* OGE Legal Advisory LA–15–03 (Apr. 9, 2015). In particular, the example notes that while certain facts alone—such as listing the employee's Government title under the ''occupation'' section of their personal social media account—would not reasonably be construed as implying governmental sanction or endorsement, it would be problematic if the EPA employee prominently featured the agency's seal on their social media account and made statements asserting or implying that their opinions on environmental topics are sanctioned or endorsed by the Government.

One agency commenter recommended updating this example to address the use of an official Government photograph on personal social media. Official photographs, displays including official uniform or insignia, and use of agency seals must be consistent with all applicable statutes, regulations, and agency policies, including the Standards. Employees who choose to display official pictures or include photographs of themselves wearing agency uniform or insignia should be mindful that doing so can increase the possibility of confusion as to whether their social media account and content on that account are official or personal; a prominent disclaimer clarifying that all content is personal can help obviate such confusion. However, OGE declines to update the example to discuss the use of an official photograph on a personal social media account. Although the new example provides an illustration of how personal social media use might implicate ethics rules regarding misuse of position, it is not intended to be exhaustive of the myriad ways that employees might engage or post on their personal social media accounts. Given the nuance of these issues, OGE believes that this topic is best addressed through interpretive guidance, and notes that it recently issued a Legal Advisory discussing the application of ethics rules to employees' activities on personal social media accounts, including the use of official photographs. *See* OGE Legal Advisory LA–23–13, at 2–3 (Sept. 28, 2023) (discussing the question ''Can I use my official picture or a picture of me at a work event as my profile picture [on social media]?'').

Acceptable Personal Use of Government Resources

As explained in the preamble to the proposed rule, OGE proposed replacing example 1 following § 2635.704(b)—which discussed a General Services Administration (GSA) regulation that no longer exists—with an example that references an agency's *de minimis* policy relating to the personal use of a Government email account. In response to this change, one individual commenter requested that OGE provide more guidance on acceptable personal use of Government resources, given the absence of a GSA regulation and significant technological changes in recent years. OGE believes the Standards and examples set forth and revised in § 2635.704 are sufficiently clear and can be applied to Government property as it continues to evolve with technological advances. Furthermore, more specific guidelines about current technology than what is already in § 2635.704 and its examples would run the risk of quickly becoming outdated. Finally, OGE notes that agencies have established more specific policies regarding acceptable limited personal use of Government resources by their employees, and employees' adherence to these policies would constitute an authorized use of Government resources. *See* OGE Inf. Adv. Op. 97x3 (Mar. 21, 1997). OGE defers to agencies to interpret such policies and to determine whether specific instances of personal use would amount to a misuse of Government resources.

H. Outside Activities (Subpart H)

Teaching, Speaking, and Writing

One individual provided comments regarding OGE's proposed ministerial change to § 2635.807(a), which emphasizes the timing aspect that an employee ''may not receive compensation from any source other than the Government for teaching, speaking, or writing that occurs *while the person is a Government employee and that relates to the employee's official duties.*'' (Emphasis added.) The commenter incorrectly suggests that the updated language provides for a ''looser standard'' than set forth in the original rule; specifically, the commenter stated that before this change, § 2635.807 had a ''broader application . . . [that] prevents former employees from gaining, after the fact from'' their official duties and that the new language would ''lessen the broad application and lift the restrictions as they would apply to former employees.''

As a threshold matter, OGE reiterates that the Standards, including subpart H, apply only to current executive branch employees. More specifically regarding teaching, speaking, and writing covered by § 2635.807, OGE has been unequivocal in its guidance that ''ethics rules do not restrict receipt of compensation unless the writing occurs during Government service.'' OGE DAEOgram DO–08–006, pt. I, at 8 (Mar. 6, 2008); *see also id.* (''Section 2635.807 applies to an individual while [they] serve[ ] as a Government employee. Therefore, each provision contained in section 2635.807 restricts compensation only for writing that occurs while an individual is in Government service. If the writing is done either before or after Government service, none of these provisions will apply.''). Accordingly, OGE declines the commenter's suggestion that § 2635.807(a) be phrased disjunctively, such that compensation for teaching, speaking, or writing would be restricted if the writing occurs while the person is a Government employee or if the writing relates to an employee's official duties.

One agency commenter characterized § 2635.807 as addressing teaching, speaking, or writing ''on 'official time' and on personal time,'' and suggested that the section be divided into off-duty and official duty paragraphs ''rather than housing it all under Outside Activities.'' OGE disagrees with the commenter's characterization. As noted in § 2635.801(a), subpart H ''contains provisions relating to outside employment, [and] outside activities''; § 2635.807 addresses teaching, speaking, and writing that an employee does as outside employment or an outside activity, and is not intended to address official duty teaching, speaking, or writing. To the extent that this section refers to official capacity teaching, speaking, and writing, it does so for limited purposes. First, it refers to official capacity activities in certain examples to distinguish between the scenarios where the requirements of § 2635.807 do and do not apply. *See, e.g.,* § 2635.807(a)(2)(iii), example 4 (describing a scenario where payments are not prohibited under the rule restricting compensation for speaking relating to official duties because the employee is speaking officially); *see also* § 2635.807(b), example 1 (noting that the restrictions on reference to official position would not apply to an employee who is authorized to speak in their official capacity). Second, it notes that ''[t]eaching, speaking, or writing relates to the employee's official duties''—and thus is covered by § 2635.807(a)—if ''[t]he activity is undertaken as part of the employee's official duties.'' This language simply ''incorporates the . . . prohibition on supplementation of salary contained in 18 U.S.C. 209,'' DO–08–006, pt. I, at 19 n.18, and is not intended to provide any specific guidance regarding official duty speaking. For these reasons, OGE declines the commenter's suggested reorganization.

The same commenter asked OGE to address various scenarios relating to the extent to which an employee could choose or refuse who they present agency information to as part of an outside activity if the presentation otherwise meets the requirements of § 2635.807(a). The scenarios posed by the commenter are very fact-specific, and unfortunately it is not feasible for OGE to include exhaustive examples in the regulation discussing the application of § 2635.807 and other ethics rules. OGE notes, however, that even if § 2635.807 would not restrict an employee's teaching, speaking, or writing, the employee may not conduct the activity in a way that violates other ethics requirements. *See, e.g.,* OGE Inf. Adv. Op. 94x1 (Jan. 10, 1994) (''If an employee does not receive any compensation for [their] participation in the conference, the speech will not be prohibited by section 2635.807. In such an instance, the primary consideration the employee should keep in mind is [their] responsibility not to misuse [their] position, title, Government property, or nonpublic information.'').

Finally, OGE declines this commenter's suggestion to impose a disclaimer requirement for official teaching, speaking, or writing. To the extent that agencies authorize or require the use of disclaimers in official speeches to make clear that the speaker is sharing their personal views rather than the views of the agency, OGE defers to agencies on whether the use of such a disclaimer is appropriate.

A different agency expressed concern regarding a minor update OGE proposed to make to the existing note to 5 CFR 2635.807(a)(2)(iii). Specifically, OGE proposed to delete the reference to 18 U.S.C. 209 in the reminder that other authorities in some circumstances may limit or preclude an employee's acceptance of travel expenses. OGE's intention in deleting the reference was not to make a substantive change but rather ''to avoid unnecessary focus on a single statute to the potential exclusion of other applicable authorities.'' 88 FR 10774, 10780 (Feb. 21, 2023). The commenter requested that OGE keep the reference to 18 U.S.C. 209 because ''[i]t is helpful to employees and legal practitioners to be reminded in this

context that a criminal statute in particular may be triggered.''

Based on this feedback, OGE will add back in the reference to 18 U.S.C. 209 in the referenced note. However, OGE reiterates that other authorities may limit or preclude an employee's acceptance of travel expenses, so to emphasize that section 209 is one of several potentially applicable authorities, OGE has updated the phrase to read ''other authorities, including but not limited to 18 U.S.C. 209.''

One agency commenter asked that OGE add new language to § 2635.807(b) permitting ethics officials to apply a fact-based, ''totality of circumstances'' test to determine whether an employee serving as faculty at Federal universities and schools may include their title or position in connection with outside academic or scientific editorial board service, and for listings of professional society committee membership. The commenter's request for a ''totality of circumstances'' test appears to be based on the commenter's assertion that, in the context of Federal employees serving as faculty at Federal universities and schools, disclaimers and biographical sketches required for teaching, speaking, and writing activities under § 2635.807(b) ''are not commonly used by publishers'' and professional societies.

As OGE has previously explained, ''[t]he foundation in the Standards underlying the limitations on use of official title is 5 CFR 2635.702(b), which provides 'an employee shall not use or permit the use of [their] Government position or title or any authority associated with [their] public office in a manner that could reasonably be construed to imply that [their] agency or the [G]overnment sanctions or endorses [their] personal activities or those of another.''' OGE Inf. Adv. Op. 10x1, at 1 (Mar. 19, 2010). Employees engaged in outside teaching, speaking, and writing must also meet the use of title requirements of § 2635.807(b). OGE has advised that ''[t]he purpose of section 807(b)(1) and (b)(2), in conjunction with section 702(b), is to ensure that public is not misled as to whether the views expressed by an Executive Branch employee in uncompensated teaching, writing, or speaking are those of the employee or those of the Government.'' *Id.* at 2.

OGE believes that the guidance it has previously issued regarding use of title in outside activities sufficiently addresses the commenter's practical concerns. *See, e.g., id.* (emphasizing the importance of an employee providing relevant biographical details other than official title and position in connection with teaching, speaking, and writing, as required by § 2635.807(b)(1), and discussing how to evaluate whether an employee has complied in good faith with this provision); *see also* OGE Legal Advisory LA–14–08, at 2 (Nov. 19, 2014) (stressing the importance of considering the totality of circumstances in connection with use of title in other outside activities, such as involvement with a professional society, to determine whether a reasonable person could construe the reference to imply sanction or endorsement of the organization or the employee's personal activities). Because OGE believes that subparts G and H and the further guidance on those provisions provide appropriate flexibility regarding use of title and sufficiently address the commenter's concerns, OGE declines to make the commenter's recommended change.

Fundraising

The same agency recommended that OGE amend the definition of ''participation in the conduct of an event'' at § 2635.808(a)(2) to clarify that the term includes presenting awards and being present on stage during the presentation of awards. OGE declines to adopt these changes given that the list of examples to which the commenter suggests adding is not intended to be exhaustive. Additionally, it is OGE's belief that the current language provides sufficient guidance for practical application of the regulation by ethics officials and employees, without being unnecessarily proscriptive regarding the necessarily fact-specific application of this provision.

The same agency also requested certain clarifications in the new social media examples added to § 2635.808(c) relating to fundraising in a personal capacity. In particular, the commenter suggested updating example 5 to note that the employee's ''personal solicitation'' could be sent by either official or personal email, and suggested updating example 6 to note that ''any person'' includes subordinates. OGE believes that the cited examples are appropriately specific, and therefore declines to incorporate these changes. Specifically, the general reference to an email transmission in example 5 does not suggest that such a transmission need be sent by either a personal or an official email to be problematic. Similarly, the reference to ''any person'' in example 6 is appropriately broad such that it could include a subordinate.

I. Other

Incorporation of Obligations From Ethics Pledges

One individual commenter recommended that OGE implement certain core provisions of recent Presidential ethics pledges that impose additional obligations on certain noncareer employees. *See, e.g.,* E.O. 13490 (Jan. 21, 2009); E.O. 13770 (Jan. 28, 2017); E.O. 13989 (Jan. 20, 2021). OGE declines to make such a change, which is outside the scope of the modernization updates contemplated by this rulemaking, and about which public input was requested. OGE further notes that it is the prerogative of each Presidential administration to determine what, if any, additional ethics obligations it wishes to impose on its appointees, and that it would not be appropriate for OGE to implement such obligations in a regulation that by design is intended to extend across multiple administrations.

Subpart J

As discussed above, OGE recently engaged in a separate rulemaking process that culminated in the addition of subpart J to the Standards. This rulemaking makes no changes to subpart J, and revises and republishes only subparts A through I of the Standards.

III. Matters of Regulatory Procedure

Regulatory Flexibility Act

As Acting Director of the Office of Government Ethics, I certify under the Regulatory Flexibility Act (5 U.S.C. chapter 6) that this final rule will not have a significant economic impact on a substantial number of small entities because it primarily affects current Federal executive branch employees.

Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) does not apply because this regulation does not contain information collection requirements that require approval of the Office of Management and Budget.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. chapter 25, subchapter II), this final rule will not significantly or uniquely affect small governments and will not result in increased expenditures by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more (as adjusted for inflation) in any one year.

Executive Orders 12866, 13563, and 14094

In promulgating this rule, the Office of Government Ethics has adhered to the regulatory philosophy and the applicable principles of regulation set forth in Executive Order 12866, Regulatory Planning and Review (58 FR 51735, Oct. 4, 1993); Executive Order 13563, Improving Regulation and Regulatory Review (76 FR 3821, Jan. 21, 2011); and Executive Order 14094, Modernizing Regulatory Review (88 FR 21879, Apr. 11, 2023). Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select the regulatory approaches that maximize net benefits (including economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

Although the number of substantive changes to the regulation is not extensive, the benefits of implementing these changes are significant. The existing regulation is not insufficient, but it has not been significantly updated since its issuance in 1992. OGE's revisions address common questions received from ethics officials, incorporate OGE's experience gained from applying the regulation since its inception, modernize existing examples and add new examples for more useful reference, provide updated citations where regulatory provisions or statutes have changed, and make technical corrections. These revisions will provide greater clarity for executive branch employees and ethics officials. Further, OGE anticipates that this additional clarity will increase compliance and reduce the number of inadvertent violations.

OGE does not anticipate any significant increased costs associated with these changes. However, OGE notes that there may be an increase in the time burden during the first year in which the regulatory updates become effective, particularly for ethics officials, due to necessary updates to training materials and other related ethics briefings, questions regarding the interpretation of revised regulatory provisions, and review of additional OGE guidance.

This rule has been designated as a ''significant regulatory action'' under Executive Order 12866, although not significant under section 3(f)(1) of Executive Order 12866. Accordingly, this rule has been reviewed by the Office of Management and Budget.

Executive Order 12988

As Acting Director of the Office of Government Ethics, I have reviewed this rule in light of section 3 of Executive Order 12988, Civil Justice Reform, and certify that it meets the applicable standards provided therein.

Executive Order 13175

The Office of Government Ethics has evaluated this final rule under the criteria set forth in Executive Order 13175 and determined that Tribal consultation is not required as this final rule has no 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.

List of Subjects in 5 CFR Part 2635

Conflict of interests, Executive branch standards of ethical conduct, Government employees.

Approved: May 8, 2024

Shelley K. Finlayson,

Acting Director, U.S. Office of Government Ethics.

For the reasons set forth in the preamble, the U.S. Office of Government Ethics amends 5 CFR part 2635 as follows:

PART 2635—STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE EXECUTIVE BRANCH

■ 1. The authority citation for part 2635 is revised to read as follows:

Authority: 5 U.S.C. 7301, 7351, 7353; 5 U.S.C. ch. 131; E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306.

■ 2. Revise and republish subparts A through I to read as follows:

Subpart A—General Provisions

Sec.

Subpart B—Gifts From Outside Sources

Subpart C—Gifts Between Employees

Subpart D—Conflicting Financial Interests

Subpart E—Impartiality in Performing Official Duties

Subpart F—Seeking Other Employment

Subpart G—Misuse of Position

Subpart H—Outside Activities

Subpart I—Related Statutory Authorities

Subpart A—General Provisions

§ 2635.101 Basic obligation of public service.

(a) *Public service is a public trust.* Each employee has a responsibility to the United States Government and its citizens to place loyalty to the Constitution, laws, and ethical principles above private gain. To ensure that every citizen can have complete confidence in the integrity of the Federal Government, each employee must respect and adhere to the principles of ethical conduct set forth in this section, as well as the implementing standards contained in this part and in supplemental agency regulations.

(b) *General principles.* The following general principles apply to every employee and may form the basis for the standards contained in this part. When a situation is not covered by the standards set forth in this part, employees must apply the principles set forth in this section in determining whether their conduct is proper.

(1) Public service is a public trust, requiring employees to place loyalty to the Constitution, the laws, and ethical principles above private gain.

(2) Employees shall not hold financial interests that conflict with the conscientious performance of duty.

(3) Employees shall not engage in financial transactions using nonpublic Government information or allow the improper use of such information to further any private interest.

(4) An employee shall not, except as permitted by subpart B of this part, solicit or accept any gift or other item of monetary value from any person or entity seeking official action from, doing business with, or conducting activities regulated by the employee's agency, or whose interests may be substantially affected by the performance or nonperformance of the employee's duties.

(5) Employees shall put forth honest effort in the performance of their duties.

(6) Employees shall not knowingly make unauthorized commitments or promises of any kind purporting to bind the Government.

(7) Employees shall not use public office for private gain.

(8) Employees shall act impartially and not give preferential treatment to any private organization or individual.

(9) Employees shall protect and conserve Federal property and shall not use it for other than authorized activities.

(10) Employees shall not engage in outside employment or activities, including seeking or negotiating for employment, that conflict with official Government duties and responsibilities.

(11) Employees shall disclose waste, fraud, abuse, and corruption to appropriate authorities.

(12) Employees shall satisfy in good faith their obligations as citizens, including all just financial obligations, especially those—such as Federal, State, or local taxes—that are imposed by law.

(13) Employees shall adhere to all laws and regulations that provide equal opportunity for all Americans regardless of, for example, race, color, religion, sex (including pregnancy, gender identity, and sexual orientation), national origin, age, genetic information, or disability.

(14) Employees shall endeavor to avoid any actions creating the appearance that they are violating the law or the ethical standards set forth in this part. Whether particular circumstances create an appearance that the law or these standards have been violated shall be determined from the perspective of a reasonable person with knowledge of the relevant facts.

(c) *Related statutes.* In addition to the standards of ethical conduct set forth in this part, there are conflict of interest statutes that prohibit certain conduct. Criminal conflict of interest statutes of general applicability to all employees, 18 U.S.C. 201, 203, 205, 208, and 209, are summarized in the appropriate subparts of this part and must be taken into consideration in determining whether conduct is proper. Citations to other generally applicable statutes relating to employee conduct are set forth in subpart I of this part, and employees are further cautioned that there may be additional statutory and regulatory restrictions applicable to them generally or as employees of their specific agencies. Because an employee is considered to be on notice of the requirements of any statute, an employee should not rely upon any description or synopsis of a statutory restriction, but should refer to the statute itself and obtain the advice of an agency ethics official as needed.

§ 2635.102 Definitions.

The definitions listed in this section are used throughout this part. Additional definitions appear in the subparts or sections of subparts to which they apply. For purposes of this part:

(a) *Agency* means an executive agency as defined in 5 U.S.C. 105 and the Postal Service and the Postal Regulatory Commission. It does not include the Government Accountability Office or the government of the District of Columbia.

(b) *Agency designee* refers to any employee who, by agency regulation, instruction, or other issuance, has been delegated authority to make any determination, give any approval, or take any other action required or permitted by this part with respect to another employee. An agency may delegate these authorities to any number of agency designees necessary to ensure that determinations are made, approvals are given, and other actions are taken in a timely and responsible manner. Any provision that requires a determination, approval, or other action by the agency designee will, when the conduct in issue is that of the head of the agency, be deemed to require that such determination, approval, or action be made or taken by the head of the agency in consultation with the designated agency ethics official.

(c) *Agency ethics official* refers to the designated agency ethics official, the alternate designated agency ethics official, any deputy ethics official, and any additional ethics official who has been delegated authority to assist in carrying out the responsibilities of an agency's ethics program. The responsibilities of agency ethics officials are described in § 2638.104 of this chapter.

(d) *Agency programs or operations* refers to any program or function carried out or performed by an agency, whether pursuant to statute, Executive order, or regulation.

(e) *Corrective action* includes any action necessary to remedy a past violation or prevent a continuing violation of this part, including but not limited to restitution, change of assignment, recusal, divestiture, termination of an activity, waiver, the creation of a qualified diversified or blind trust, or counseling.

(f) *Designated agency ethics official* refers to the official designated under § 2638.104(a) of this chapter.

(g) *Disciplinary action* includes those disciplinary actions referred to in Office of Personnel Management regulations at 5 CFR chapter I and instructions implementing provisions of title 5 of the United States Code or provided for in comparable provisions applicable to employees not subject to title 5, including but not limited to reprimand, suspension, demotion, and removal. In the case of a military officer, comparable provisions may include those in the Uniform Code of Military Justice.

(h) *Employee* means any officer or employee of an agency, including a special Government employee. It includes officers but not enlisted members of the uniformed services. It includes employees of a State or local

government or other organization who are serving on detail to an agency, pursuant to 5 U.S.C. 3371, *et seq.* For purposes other than subparts B and C of this part, it does not include the President or Vice President. Status as an employee is unaffected by pay or leave status or, in the case of a special Government employee, by the fact that the individual does not perform official duties on a given day.

(i) *Head of an agency* means, in the case of an agency headed by more than one person, the chair or comparable member of such agency.

(j) *Person* means an individual, corporation and subsidiaries it controls, company, association, firm, partnership, society, joint stock company, or any other organization or institution, including any officer, employee, or agent of such person or entity. For purposes of this part, a corporation will be deemed to control a subsidiary if it owns 50 percent or more of the subsidiary's voting securities. The term is all-inclusive and applies to commercial ventures and nonprofit organizations as well as to foreign, State, and local governments, including the government of the District of Columbia. It does not include any agency or other entity of the Federal Government or any officer or employee thereof when acting in an official capacity on behalf of that agency or entity.

(k) *Special Government employee* means those executive branch officers or employees specified in 18 U.S.C. 202(a). A special Government employee is retained, designated, appointed, or employed to perform temporary duties either on a full-time or intermittent basis, with or without compensation, for a period not to exceed 130 days during any consecutive 365-day period.

(l) *Supplemental agency regulation* means a regulation issued pursuant to § 2635.105.

§ 2635.103 Applicability to enlisted members of the uniformed services.

The provisions of this part are not applicable to enlisted members of the uniformed services. However, each agency with jurisdiction over enlisted members of the uniformed services may issue regulations defining the ethical conduct obligations of enlisted members under its jurisdiction. Such regulations or policies, if issued, should be consistent with Executive Order 12674, April 12, 1989, as modified, and may prescribe the full range of statutory and regulatory sanctions, including those available under the Uniform Code of Military Justice, for failure to comply with such regulations.

§ 2635.104 Applicability to employees on detail.

(a) *Details to other agencies.* Except as provided in paragraph (d) of this section, employees on detail, including uniformed officers on assignment, from their employing agencies to another agency for a period in excess of 30 calendar days will be subject to any supplemental agency regulations of the agency to which they are detailed rather than to any supplemental agency regulations of their employing agencies.

(b) *Details to the legislative or judicial branch.* Employees on detail, including uniformed officers on assignment, from their employing agencies to the legislative or judicial branch for a period in excess of 30 calendar days will be subject to the ethical standards of the branch or entity to which detailed. For the duration of any such detail or assignment, employees will not be subject to the provisions of this part, except this section, or, except as provided in paragraph (d) of this section, to any supplemental agency regulations of their employing agencies, but will remain subject to the conflict of interest prohibitions in title 18 of the United States Code.

(c) *Details to non-Federal entities.* Except to the extent exempted in writing pursuant to this paragraph (c), an employee detailed to a non-Federal entity remains subject to this part and to any supplemental agency regulation of their employing agency. When an employee is detailed pursuant to statutory authority to an international organization or to a State or local government for a period in excess of six months, the designated agency ethics official may grant a written exemption from subpart B of this part based on their determination that the entity has adopted written ethical standards covering solicitation and acceptance of gifts which will apply to the employee during the detail and which will be appropriate given the purpose of the detail.

(d) *Applicability of special agency statutes.* Notwithstanding paragraphs (a) and (b) of this section, employees who are subject to an agency statute which restricts their activities or financial holdings specifically because of their status as an employee of that agency will continue to be subject to any provisions in the supplemental agency regulations of the employing agency that implement that statute.

§ 2635.105 Supplemental agency regulations.

In addition to the regulations set forth in this part, employees must comply with any supplemental agency regulations issued by their employing agencies under this section.

(a) An agency that wishes to supplement this part must prepare and submit to the Office of Government Ethics, for its concurrence and joint issuance, any agency regulations that supplement the regulations contained in this part. Supplemental agency regulations which the agency determines are necessary and appropriate, in view of its programs and operations, to fulfill the purposes of this part must be:

(1) In the form of a supplement to the regulations in this part; and

(2) In addition to the substantive provisions of this part.

(b) After concurrence and co-signature by the Office of Government Ethics, the agency must submit its supplemental agency regulations to the **Federal Register** for publication and codification at the expense of the agency in this title. Supplemental agency regulations issued under this section are effective only after concurrence and co-signature by the Office of Government Ethics and publication in the **Federal Register**.

(c) This section applies to any supplemental agency regulations or amendments thereof issued under this part. It does not apply to:

(1) A handbook or other issuance intended merely as an explanation of the standards contained in this part or in supplemental agency regulations;

(2) An instruction or other issuance the purpose of which is to:

(i) Delegate to an agency designee authority to make any determination, give any approval or take any other action required or permitted by this part or by supplemental agency regulations; or

(ii) Establish internal agency procedures for documenting or processing any determination, approval or other action required or permitted by this part or by supplemental agency regulations, or for retaining any such documentation; or

(3) Regulations or instructions that an agency has authority, independent of this part, to issue, such as regulations implementing an agency's gift acceptance statute, protecting categories of nonpublic information, or establishing standards for use of Government vehicles.

(d) Employees of a State or local government or other organization who are serving on detail to an agency, pursuant to 5 U.S.C. 3371, *et seq.,* are subject to any requirements, in addition to those in this part, established by a supplemental agency regulation issued under this section to the extent that such regulation expressly provides.

§ 2635.106 Disciplinary and corrective action.

(a) Except as provided in § 2635.107, a violation of this part or of supplemental agency regulations may be cause for appropriate corrective or disciplinary action to be taken under applicable Governmentwide regulations or agency procedures. Such action may be in addition to any action or penalty prescribed by law.

(b) It is the responsibility of the employing agency to initiate appropriate disciplinary or corrective action in individual cases. However, corrective action may be ordered or disciplinary action recommended by the Director of the Office of Government Ethics under the procedures at part 2638 of this chapter.

(c) A violation of this part or of supplemental agency regulations, as such, does not create any right or benefit, substantive or procedural, enforceable at law by any person against the United States, its agencies, its officers or employees, or any other person. Thus, for example, an individual who alleges that an employee has failed to adhere to laws and regulations that provide equal opportunity regardless of race, color, religion, sex (including pregnancy, gender identity, and sexual orientation), national origin, age, genetic information, or disability is required to follow applicable statutory and regulatory procedures, including those of the Equal Employment Opportunity Commission.

§ 2635.107 Ethics advice.

(a) As required by § 2638.104(a) and (d) of this chapter, each agency has a designated agency ethics official and an alternate designated agency ethics official; these are the employees who have the primary responsibility for directing the daily activities of an agency's ethics program. Acting directly or through other officials, the designated agency ethics official is responsible for providing ethics advice and counseling regarding the application of this part.

(b) Employees who have questions about the application of this part or any supplemental agency regulations to particular situations should seek advice from an agency ethics official. Disciplinary action for violating this part or any supplemental agency regulations will not be taken against an employee who has engaged in conduct in good faith reliance upon the advice of an agency ethics official, provided that the employee, in seeking such advice, has made full disclosure of all relevant circumstances. When the employee's conduct violates a criminal statute, reliance on the advice of an agency ethics official cannot ensure that the employee will not be prosecuted under that statute. However, good faith reliance on the advice of an agency ethics official is a factor that may be taken into account by the Department of Justice in the selection of cases for prosecution. Disclosures made by an employee to an agency ethics official are not protected by an attorney-client privilege. Agency ethics officials are required by 28 U.S.C. 535 to report any information they receive relating to a violation of the criminal code, title 18 of the United States Code.

Subpart B—Gifts From Outside Sources

§ 2635.201 Overview and considerations for declining otherwise permissible gifts.

(a) *Overview.* This subpart contains standards that prohibit an employee from soliciting or accepting any gift from a prohibited source or any gift given because of the employee's official position, unless the item is excluded from the definition of a *gift* (see § 2635.203(b)) or falls within one of the exceptions set forth in this subpart.

(b) *Considerations for declining otherwise permissible gifts.* (1) Every employee has a fundamental responsibility to the United States and its citizens to place loyalty to the Constitution, laws, and ethical principles above private gain. An employee's actions should promote the public's trust that this responsibility is being met. For this reason, employees should consider declining otherwise permissible gifts if they believe that a reasonable person with knowledge of the relevant facts would question the employee's integrity or impartiality as a result of accepting the gift.

(2) Employees who are considering whether acceptance of a gift would lead a reasonable person with knowledge of the relevant facts to question their integrity or impartiality may consider, among other relevant factors, whether:

(i) The gift has a high market value;

(ii) The timing of the gift creates the appearance that the donor is seeking to influence an official action;

(iii) The gift was provided by a person who has interests that may be substantially affected by the performance or nonperformance of the employee's official duties; and

(iv) Acceptance of the gift would provide the donor with significantly disproportionate access.

(3) Notwithstanding paragraph (b)(1) of this section, an employee who accepts a gift that qualifies for an exception under § 2635.204 does not violate this subpart or the Principles of Ethical Conduct set forth in § 2635.101(b).

(4) Employees who have questions regarding this subpart, including whether the employee should decline a gift that would otherwise be permitted under an exception found in § 2635.204, should seek advice from an agency ethics official.

Example 1 to paragraph (b): An employee of the Peace Corps is in charge of making routine purchases of office supplies. After a promotional presentation to highlight several new products, a vendor offers to buy the employee lunch, which costs less than $20. The employee is concerned that a reasonable person may question their impartiality by accepting the free lunch, as the timing of the offer indicates that the donor may be seeking to influence an official action and the company has interests that may be substantially affected by the performance or nonperformance of the employee's duties. The employee concludes that appearance considerations weigh against accepting the gift.

§ 2635.202 General prohibition on solicitation or acceptance of gifts.

(a) *Prohibition on soliciting gifts.* Except as provided in this subpart, an employee may not, directly or indirectly:

(1) Solicit a gift from a prohibited source; or

(2) Solicit a gift to be given because of the employee's official position.

(b) *Prohibition on accepting gifts.* Except as provided in this subpart, an employee may not, directly or indirectly:

(1) Accept a gift from a prohibited source; or

(2) Accept a gift given because of the employee's official position.

(c) *Relationship to illegal gratuities statute.* A gift accepted pursuant to an exception found in this subpart will not constitute an illegal gratuity otherwise prohibited by 18 U.S.C. 201(c)(1)(B), unless it is accepted in return for being influenced in the performance of an official act. As more fully described in § 2635.205(d)(1), an employee may not solicit or accept a gift if to do so would be prohibited by the Federal bribery statute, 18 U.S.C. 201(b).

Example 1 to paragraph (c): A Government contractor who specializes in information technology software has offered an employee of the Department of Energy's information technology acquisition division a $15 gift card to a local restaurant if the employee will recommend to the agency's contracting officer that the agency select the contractor's products during the next

acquisition. Even though the gift card is less than $20, the employee may not accept the gift under § 2635.204(a) because it is conditional upon official action by the employee. Pursuant to this paragraph (c) and § 2635.205(a), notwithstanding any exception to the rules in this part, an employee may not accept a gift in return for being influenced in the performance of an official act.

§ 2635.203 Definitions.

For purposes of this subpart, the following definitions apply:

(a) *Agency* has the meaning set forth in § 2635.102(a). However, for purposes of this subpart, an executive department, as defined in 5 U.S.C. 101, may, by supplemental agency regulation, designate as a separate agency any component of that department which the department determines exercises distinct and separate functions.

(b) *Gift* includes any gratuity, favor, discount, entertainment, hospitality, loan, forbearance, or other item having monetary value. It includes services as well as gifts of training, transportation, local travel, lodgings, and meals, whether provided in-kind, by purchase of a ticket, payment in advance, or reimbursement after the expense has been incurred. The term excludes the following:

(1) Modest items of food and non-alcoholic refreshments, such as soft drinks, coffee, and donuts, offered other than as part of a meal;

Example 1 to paragraph (b)(2): After giving a speech at the facility of a pharmaceutical company, a Government employee is presented with a glass paperweight in the shape of a pill capsule with the name of the company's latest drug and the date of the speech imprinted on the side. The employee may accept the paperweight because it is an item with little intrinsic value which is intended primarily for presentation.

Example 2 to paragraph (b)(2): After participating in a panel discussion hosted by an international media company, a Government employee is presented with an inexpensive portable music player emblazoned with the media company's logo. The portable music player has a market value of $25. The employee may not accept the portable music player as it has a significant independent use as a music player rather than being intended primarily for presentation.

Example 3 to paragraph (b)(2): After giving a speech at a conference held by a national association of miners, a Department of Commerce employee is presented with a block of granite that is engraved with the association's logo, a picture of the Appalachian Mountains, the date of the speech, and the employee's name. The employee may accept this item because it is similar to a plaque, is designed primarily for presentation, and has little intrinsic value.

(3) Loans from banks and other financial institutions on terms generally available to the public;

(4) Opportunities and benefits, including favorable rates, commercial discounts, and free attendance or participation available to the public or to a class consisting of all Government employees or all uniformed military personnel, whether or not restricted on the basis of geographic considerations;

(5) Rewards and prizes given to competitors in contests or events, including random drawings, open to the public unless the employee's entry into the contest or event is required as part of the employee's official duties;

Example 1 to paragraph (b)(5): A Government employee is attending a free trade show on official time. The trade show is held in a public shopping area adjacent to the employee's office building. The employee voluntarily enters a drawing at an individual vendor's booth, which is open to the public, by filling in an entry form on the vendor's display table and dropping it into the contest box. The employee may accept the resulting prize because entry into the contest was not required by or related to their official duties.

Example 2 to paragraph (b)(5): Attendees at a conference, which is not open to the public, are entered in a drawing for a weekend getaway to Bermuda as a result of being registered for the conference. A Government employee who attends the conference in an official capacity could not accept the prize under paragraph (b)(5) of this section, as the event is not open to the public.

(6) Pension and other benefits resulting from continued participation in an employee welfare and benefits plan maintained by a current or former employer;

(7) Anything which is paid for by the Government or secured by the Government under Government contract;

Example 1 to paragraph (b)(7): An employee at the Occupational Safety and Health Administration is assigned to travel away from their duty station to conduct an investigation of a collapse at a construction site. The employee's agency is paying for relevant travel expenses, including airfare. The employee may accept and retain travel promotional items, such as frequent flyer miles, received as a result of this official travel, to the extent permitted by 5 U.S.C. 5702 note and 41 CFR part 301–53.

(8) Free attendance to an event provided by the sponsor of the event to:

(i) An employee who is assigned to present information on behalf of the agency at the event on any day when the employee is presenting;

(ii) An employee whose presence on any day of the event is deemed to be essential by the agency to the presenting employee's participation in the event, provided that the employee is accompanying the presenting employee; and

(iii) One guest of the presenting employee on any day when the employee is presenting, provided that others in attendance will generally be accompanied by a guest, the offer of free attendance for the guest is unsolicited, and the agency designee, orally or in writing, has authorized the presenting employee to accept;

Example 1 to paragraph (b)(8): An employee of the Department of the Treasury who is assigned to participate in a panel discussion of economic issues as part of a one-day conference may accept the sponsor's waiver of the conference fee. Under the separate authority of § 2635.204(a), the employee may accept a token of appreciation that has a market value of $20 or less.

Example 2 to paragraph (b)(8): An employee of the Securities and Exchange Commission is assigned to present the agency's views at a roundtable discussion of an ongoing working group. The employee may accept free attendance to the meeting under paragraph (b)(8) of this section because the employee has been assigned to present information at the meeting on behalf of the agency. If it is determined by the agency that it is essential that other employees accompany the presenting employee to the roundtable discussion, the accompanying employees may also accept free attendance to the meeting under paragraph (b)(8)(ii) of this section.

Example 3 to paragraph (b)(8): An employee of the United States Trade and Development Agency is invited to attend a cocktail party hosted by a prohibited source. The employee believes that there will be an opportunity to discuss official matters with other attendees while at the event. Although the employee may voluntarily discuss official matters with other

attendees, the employee has not been assigned to present information on behalf of the agency. The employee may not accept free attendance to the event under paragraph (b)(8) of this section.

(9) Any gift accepted by the Government under specific statutory authority, including:

(i) Travel, subsistence, and related expenses accepted by an agency under the authority of 31 U.S.C. 1353 in connection with an employee's attendance at a meeting or similar function relating to the employee's official duties which take place away from the employee's duty station, provided that the agency's acceptance is in accordance with the implementing regulations at 41 CFR chapter 304; and

(ii) Other gifts provided in-kind which have been accepted by an agency under its agency gift acceptance statute; and

(10) Anything for which market value is paid by the employee.

(c) *Market value* means the cost that a member of the general public would reasonably expect to incur to purchase the gift. An employee who cannot ascertain the market value of a gift may estimate its market value by reference to the retail cost of similar items of like quality. The market value of a gift of a ticket entitling the holder to food, refreshments, entertainment, or any other benefit is deemed to be the face value of the ticket.

Example 1 to paragraph (c): An employee who has been given a watch inscribed with the corporate logo of a prohibited source may determine its market value based on the observation that a comparable watch, not inscribed with a logo, generally sells for about $50.

Example 2 to paragraph (c): During an official visit to a factory operated by a well-known athletic footwear manufacturer, an employee of the Department of Labor is offered a commemorative pair of athletic shoes manufactured at the factory. Although the cost incurred by the donor to manufacture the shoes was $17, the market value of the shoes would be the $100 that the employee would have to pay for the shoes on the open market.

Example 3 to paragraph (c): A prohibited source has offered a Government employee a ticket to a charitable event consisting of a cocktail reception to be followed by an evening of chamber music. Even though the food, refreshments, and entertainment provided at the event may be worth only $20, the market value of the ticket is its $250 face value.

Example 4 to paragraph (c): A company offers an employee of the Federal Communication Commission (FCC) free attendance for two to a private skybox at a ballpark to watch a major league baseball game. The skybox is leased annually by the company, which has business pending before the FCC. The skybox tickets provided to the employee do not have a face value. To determine the market value of the tickets, the employee must add the face value of two of the most expensive publicly available tickets to the game and the market value of any food, parking, or other tangible benefits provided in connection with the gift of attendance that are not already included in the cost of the most expensive publicly available tickets.

Example 5 to paragraph (c): An employee of the Department of Agriculture is invited to a reception held by a prohibited source. There is no entrance fee to the reception event or to the venue. To determine the market value of the gift, the employee must add the market value of any entertainment, food, beverages, or other tangible benefit provided to attendees in connection with the reception, but need not consider the cost incurred by the sponsor to rent or maintain the venue where the event is held. The employee may rely on a per-person cost estimate provided by the sponsor of the event, unless the employee or an agency designee has determined that a reasonable person would find that the estimate is clearly implausible.

(d) *Prohibited source* means any person who:

(1) Is seeking official action by the employee's agency;

(2) Does business or seeks to do business with the employee's agency;

(3) Conducts activities regulated by the employee's agency;

(4) Has interests that may be substantially affected by the performance or nonperformance of the employee's official duties; or

(5) Is an organization a majority of whose members are described in paragraphs (d)(1) through (4) of this section.

(e) A gift is *given because of the employee's official position* if the gift is from a person other than an employee and would not have been given had the employee not held the status, authority, or duties associated with the employee's Federal position.

Note 1 to paragraph (e): Gifts between employees are subject to the limitations set forth in subpart C of this part.

Example 1 to paragraph (e): When free season tickets are offered by an opera guild to all members of the Cabinet, the gift is offered because of their official positions.

Example 2 to paragraph (e): Employees at a regional office of the Department of Justice (DOJ) work in Government-leased space at a private office building, along with various private business tenants. A major fire in the building during normal office hours causes a traumatic experience for all occupants of the building in making their escape, and it is the subject of widespread news coverage. A corporate hotel chain, which does not meet the definition of a *prohibited source* for DOJ, seizes the moment and announces that it will give a free night's lodging to all building occupants and their families, as a public goodwill gesture. Employees of DOJ may accept, as this gift is not being given because of their Government positions. The donor's motivation for offering this gift is unrelated to the DOJ employees' status, authority, or duties associated with their Federal positions, but instead is based on their mere presence in the building as occupants at the time of the fire.

(f) A gift which is *solicited or accepted indirectly* includes a gift:

(1) Given with the employee's knowledge and acquiescence to the employee's parent, sibling, spouse, child, dependent relative, or a member of the employee's household because of that person's relationship to the employee; or

(2) Given to any other person, including any charitable organization, on the basis of designation, recommendation, or other specification by the employee, except the employee has not indirectly solicited or accepted a gift by the raising of funds or other support for a charitable organization if done in accordance with § 2635.808.

Example 1 to paragraph (f)(2): An employee who must decline a gift of a personal computer pursuant to this subpart may not suggest that the gift be given instead to one of five charitable organizations whose names are provided by the employee.

(g) *Free attendance* includes waiver of all or part of the fee for an event or the provision of food, refreshments, entertainment, instruction, or materials furnished to all attendees as an integral part of the event. It does not include travel expenses, lodgings, or entertainment collateral to the event. It does not include meals taken other than in a group setting with all other attendees, unless the employee is a presenter at the event and is invited to a separate meal for participating presenters that is hosted by the sponsor of the event. When the offer of free attendance has been extended to an accompanying guest, the market value of the gift of free attendance includes

the market value of free attendance by both the employee and the guest.

(h) *Legal expense fund* has the meaning set forth in § 2635.1003.

(i) *Pro bono legal services* has the meaning set forth in § 2635.1003.

§ 2635.204 Exceptions to the prohibition for acceptance of certain gifts.

Subject to the limitations in § 2635.205, this section establishes exceptions to the prohibitions set forth in § 2635.202(a) and (b). Even though acceptance of a gift may be permitted by one of the exceptions contained in this section, it is never inappropriate and frequently prudent for an employee to decline a gift if acceptance would cause a reasonable person to question the employee's integrity or impartiality. Section 2635.201(b) identifies considerations for declining otherwise permissible gifts.

(a) *Gifts of $20 or less.* An employee may accept unsolicited gifts having an aggregate market value of $20 or less per source per occasion, provided that the aggregate market value of individual gifts received from any one person under the authority of this paragraph (a) does not exceed $50 in a calendar year. The exception in this paragraph (a) does not apply to gifts of cash or of investment interests such as stock, bonds, or certificates of deposit. When the market value of a gift or the aggregate market value of gifts offered on any single occasion exceeds $20, the employee may not pay the excess value over $20 in order to accept that portion of the gift or those gifts worth $20. When the aggregate value of tangible items offered on a single occasion exceeds $20, the employee may decline any distinct and separate item in order to accept those items aggregating $20 or less.

Example 1 to paragraph (a): An employee of the Securities and Exchange Commission and their spouse have been invited by a representative of a regulated entity to a community theater production, tickets to which have a face value of $30 each. The aggregate market value of the gifts offered on this single occasion is $60, $40 more than the $20 amount that may be accepted for a single event or presentation. The employee may not accept the gift of the evening of entertainment. The couple may attend the play only if the employee pays the full $60 value of the two tickets.

Example 2 to paragraph (a): An employee of the National Geospatial-Intelligence Agency has been invited by an association of cartographers to speak about the agency's role in the evolution of missile technology. At the conclusion of the speech, the association presents the employee a framed map with a market value of $18 and a ceramic mug that has a market value of $15. The employee may accept the map or the mug, but not both, because the aggregate value of these two tangible items exceeds $20.

Example 3 to paragraph (a): On four occasions during the calendar year, an employee of the Defense Logistics Agency (DLA) was given gifts worth $10 each by four employees of a corporation that is a DLA contractor. For purposes of applying the yearly $50 limitation on gifts of $20 or less from any one person, the four gifts must be aggregated because a person is defined at § 2635.102(k) to mean not only the corporate entity, but its officers and employees as well. However, for purposes of applying the $50 aggregate limitation, the employee would not have to include the value of a birthday present received from a cousin, who is employed by the same corporation, if the cousin's birthday present can be accepted under the exception at paragraph (b) of this section for gifts based on a personal relationship.

Example 4 to paragraph (a): Under the authority of 31 U.S.C. 1353 for agencies to accept payments from non-Federal sources in connection with attendance at certain meetings or similar functions, the Environmental Protection Agency (EPA) has accepted an association's gift of travel expenses and conference fees for an employee to attend a conference on the long-term effect of radon exposure. While at the conference, the employee may accept a gift basket of $20 or less from one of the companies underwriting the event even though it was not approved in advance by the EPA. Although 31 U.S.C. 1353 is the authority under which the EPA accepted the gift to the agency of travel expenses and conference fees, the gift basket is a gift to the employee rather than to the EPA.

Example 5 to paragraph (a): During off-duty time, an employee of the Department of Defense (DoD) attends a trade show involving companies that are DoD contractors. The employee is offered software worth $15 at X Company's booth, a calendar worth $12 at Y Company's booth, and a deli lunch worth $8 from Z Company. The employee may accept all three of these items because they do not exceed $20 per source, even though they total more than $20 at this single occasion.

Example 6 to paragraph (a): An employee of the Department of Defense (DoD) is being promoted to a higher level position in another DoD office. Six individuals, each employed by a different defense contractor, who have worked with the DoD employee over the years, decide to act in concert to pool their resources to buy the employee a nicer gift than each could buy separately. Each defense contractor employee contributes $20 to buy a desk clock for the DoD employee that has a market value of $120. Although each of the contributions does not exceed the $20 limit, the employee may not accept the $120 gift because it is a single gift that has a market value in excess of $20.

Example 7 to paragraph (a): During a holiday party, an employee of the Department of State is given a $15 store gift card to a national coffee chain by an agency contractor. The employee may accept the card as the market value is less than $20. The employee could not, however, accept a gift card that is issued by a credit card company or other financial institution, because such a card is equivalent to a gift of cash.

(b) *Gifts based on a personal relationship.* An employee may accept a gift given by an individual under circumstances which make it clear that the gift is motivated by a family relationship or personal friendship rather than the position of the employee. Relevant factors in making such a determination include the history and nature of the relationship and whether the family member or friend personally pays for the gift.

Example 1 to paragraph (b): An employee of the Federal Deposit Insurance Corporation (FDIC) has been dating an accountant employed by a member bank. As part of its ''Work-Life Balance'' program, the bank has given each employee in the accountant's division two tickets to a professional basketball game and has urged each to invite a family member or friend to share the evening of entertainment. Under the circumstances, the FDIC employee may accept the invitation to attend the game. Even though the tickets were initially purchased by the member bank, they were given without reservation to the accountant to use as desired, and the invitation to the employee was motivated by their personal friendship.

Example 2 to paragraph (b): Three partners in a law firm that handles corporate mergers have invited an employee of the Federal Trade Commission (FTC) to join them in a golf tournament at a private club at the firm's expense. The entry fee is $500 per foursome. The employee cannot accept the gift of one-quarter of the entry fee even though the employee has developed an amicable relationship with the three partners as a result of the firm's dealings with the FTC. As

evidenced in part by the fact that the fees are to be paid by the firm, it is not a personal friendship but a business relationship that is the motivation behind the partners' gift.

Example 3 to paragraph (b): A Peace Corps employee enjoys using a social media site on the internet in a personal capacity outside of work. The employee has used the site to keep in touch with friends, neighbors, coworkers, professional contacts, and other individuals they have met over the years through both work and personal activities. One of these individuals works for a contractor that provides language services to the Peace Corps. The employee was acting in an official capacity when they met the individual at a meeting to discuss a matter related to the contract between their respective employers. Thereafter, the two communicated occasionally regarding contract matters, and later also granted one another access to join their social media networks through their respective social media accounts. However, the pair did not communicate further in their personal capacities, carry on extensive personal interactions, or meet socially outside of work. One day, the individual, whose employer continues to serve as a Peace Corps contractor, contacts the employee to offer a pair of concert tickets worth $30 apiece. Although the employee and the individual are connected through social media, the circumstances do not demonstrate that the gift was clearly motivated by a personal relationship, rather than the position of the employee, and therefore the employee may not accept the gift pursuant to paragraph (b) of this section.

(c) *Discounts and similar benefits.* In addition to those opportunities and benefits excluded from the definition of a *gift* by § 2635.203(b)(4), an employee may accept:

(1) A reduction or waiver of the fees for membership or other fees for participation in organization activities offered to all Government employees or all uniformed military personnel by professional organizations if the only restrictions on membership relate to professional qualifications; and

(2) Opportunities and benefits, including favorable rates, commercial discounts, and free attendance or participation not precluded by paragraph (c)(3) of this section:

(i) Offered to members of a group or class in which membership is unrelated to Government employment;

(ii) Offered to members of an organization, such as an employees' association or agency credit union, in which membership is related to Government employment if the same offer is broadly available to large segments of the public through organizations of similar size;

(iii) Offered by a person who is not a prohibited source to any group or class that is not defined in a manner that specifically discriminates among Government employees on the basis of type of official responsibility or on a basis that favors those of higher rank or rate of pay; or

(iv) Offered to employees by an established employee organization, such as an association composed of Federal employees or a nonprofit employee welfare organization, because of the employees' Government employment, so long as the employee is part of the class of individuals eligible for assistance from the employee organization as set forth in the organization's governing documents.

Example 1 to paragraph (c)(2): A computer company offers a discount on the purchase of computer equipment to all public and private sector computer procurement officials who work in organizations with over 300 employees. An employee who works as the computer procurement official for a Government agency could not accept the discount to purchase the personal computer under the exception in paragraph (c)(2)(i) of this section. The employee's membership in the group to which the discount is offered is related to Government employment because membership is based on the employee's status as a procurement official with the Government.

Example 2 to paragraph (c)(2): An employee of the Consumer Product Safety Commission (CPSC) may accept a discount of $50 on a microwave oven offered by the manufacturer to all members of the CPSC employees' association. Even though the CPSC is currently conducting studies on the safety of microwave ovens, the $50 discount is a standard offer that the manufacturer has made broadly available through a number of employee associations and similar organizations to large segments of the public.

Example 3 to paragraph (c)(2): An Assistant Secretary may not accept a local country club's offer of membership to all members of Department Secretariats which includes a waiver of its $5,000 membership initiation fee. Even though the country club is not a prohibited source, the offer discriminates in favor of higher-ranking officials.

Example 4 to paragraph (c)(2): A nonprofit military relief society provides access to financial counseling services, loans, and grants to all sailors and Marines. A service member may accept financial benefits from the relief society, including to cover legal expenses, because the benefits are offered by an employee organization that was established before the legal matter arose, and because the benefits are being offered because of the employees' Government employment, as set forth in the relief society's governing documents.

(3) An employee may not accept for personal use any benefit to which the Government is entitled as the result of an expenditure of Government funds, unless authorized by statute or regulation (*e.g.,* 5 U.S.C. 5702 note, regarding frequent flyer miles).

Example 1 to paragraph (c)(3): The administrative officer for a field office of U.S. Immigration and Customs Enforcement (ICE) has signed an order to purchase 50 boxes of photocopy paper from a supplier whose literature advertises that it will give a free briefcase to anyone who purchases 50 or more boxes. Because the paper was purchased with ICE funds, the administrative officer cannot keep the briefcase which, if claimed and received, is Government property.

(d) *Awards and honorary degrees*—(1) *Awards.* An employee may accept a bona fide award for meritorious public service or achievement and any item incident to the award, provided that:

(i) The award and any item incident to the award are not from a person who has interests that may be substantially affected by the performance or nonperformance of the employee's official duties, or from an association or other organization if a majority of its members have such interests; and

(ii) If the award or any item incident to the award is in the form of cash or an investment interest, or if the aggregate value of the award and any item incident to the award, other than free attendance to the event provided to the employee and to members of the employee's family by the sponsor of the event, exceeds $200, the agency ethics official has made a written determination that the award is made as part of an established program of recognition.

Example 1 to paragraph (d)(1): Based on a written determination by an agency ethics official that the prize meets the criteria set forth in paragraph (d)(2) of this section, an employee of the National Institutes of Health (NIH) may accept the Nobel Prize for Medicine, including the cash award which accompanies the prize, even though the prize was conferred on the basis of laboratory work performed at NIH.

Example 2 to paragraph (d)(1): A defense contractor, ABC Systems, has an annual award program for the outstanding public employee of the year. The award includes a cash payment of $1,000. The award program is wholly funded to ensure its continuation on a regular basis for the next twenty years and selection of award recipients is made pursuant to written standards. An employee of the Department of the Air Force, who has duties that include overseeing contract performance by ABC Systems, is selected to receive the award. The employee may not accept the cash award because ABC Systems has interests that may be substantially affected by the performance or nonperformance of the employee's official duties.

Example 3 to paragraph (d)(1): An ambassador selected by a nonprofit organization as a recipient of its annual award for distinguished service in the interest of world peace may, together with their spouse and children, attend the awards ceremony dinner and accept a crystal bowl worth $200 presented during the ceremony. However, if the organization has also offered airline tickets for the ambassador and the family to travel to the city where the awards ceremony is to be held, the aggregate value of the tickets and the crystal bowl exceeds $200, and the ambassador may accept only upon a written determination by the agency ethics official that the award is made as part of an established program of recognition.

(2) *Established program of recognition.* An award and an item incident to the award are made pursuant to an established program of recognition if:

(i) Awards have been made on a regular basis or, if the program is new, there is a reasonable basis for concluding that awards will be made on a regular basis based on funding or funding commitments; and

(ii) Selection of award recipients is made pursuant to written standards.

(3) *Honorary degrees.* An employee may accept an honorary degree from an institution of higher education, as defined at 20 U.S.C. 1001, or from a similar foreign institution of higher education, based on a written determination by an agency ethics official that the timing of the award of the degree would not cause a reasonable person to question the employee's impartiality in a matter affecting the institution.

Note 1 to paragraph (d)(3): When the honorary degree is offered by a foreign institution of higher education, the agency may need to make a separate determination as to whether the institution of higher education is a foreign government for purposes of the Emoluments Clause of the U.S. Constitution (U.S. Const., art. I, sec. 9, cl. 8), which forbids employees from accepting emoluments, presents, offices, or titles from foreign governments, without the consent of Congress. The Foreign Gifts and Decorations Act, 5 U.S.C. 7342, however, may permit the acceptance of honorary degrees in some circumstances.

Example 1 to paragraph (d)(3): A well-known university located in the United States wishes to give an honorary degree to the Secretary of Labor. The Secretary may accept the honorary degree only if an agency ethics official determines in writing that the timing of the award of the degree would not cause a reasonable person to question the Secretary's impartiality in a matter affecting the university.

(4) *Presentation events.* An employee who may accept an award or honorary degree pursuant to paragraph (d)(1) or (3) of this section may also accept free attendance to the event provided to the employee and to members of the employee's family by the sponsor of an event. In addition, the employee may also accept unsolicited offers of travel to and from the event provided to the employee and to members of the employee's family by the sponsor of the event. Travel expenses accepted under this paragraph (d)(4) must be added to the value of the award for purposes of determining whether the aggregate value of the award exceeds $200.

(e) *Gifts based on outside business or employment relationships.* An employee may accept meals, lodgings, transportation, and other benefits:

(1) Resulting from the business or employment activities of an employee's spouse when it is clear that such benefits have not been offered or enhanced because of the employee's official position;

Example 1 to paragraph (e)(1): A Department of Agriculture employee whose spouse is a computer programmer employed by a Department of Agriculture contractor may attend the company's annual retreat for all of its employees and their families held at a resort facility. However, under § 2635.502, the employee may need to recuse from performing official duties affecting the spouse's employer.

Example 2 to paragraph (e)(1): When the spouses of other clerical personnel have not been invited, an employee of the Defense Contract Audit Agency whose spouse is a clerical worker at a defense contractor may not attend the contractor's annual retreat in Hawaii for corporate officers and members of the board of directors, even though the spouse received a special invitation from the company for them to attend as a couple.

(2) Resulting from the employee's outside business or employment activities when it is clear that such benefits are based on the outside business or employment activities and have not been offered or enhanced because of the employee's official status;

Example 1 to paragraph (e)(2): The members of an Army Corps of Engineers environmental advisory committee that meets six times per year are special Government employees. A member who has a consulting business may accept an invitation to a $50 dinner from a corporate client, an Army construction contractor, unless, for example, the invitation was extended in order to discuss the activities of the advisory committee.

(3) Customarily provided by a prospective employer in connection with bona fide employment discussions. If the prospective employer has interests that could be affected by performance or nonperformance of the employee's duties, acceptance is permitted only if the employee first has complied with the recusal requirements of subpart F of this part applicable when seeking employment; or

Example 1 to paragraph (e)(3): An employee of the Federal Communications Commission with responsibility for drafting regulations affecting all cable television companies wishes to apply for a job opening with a cable television holding company. Once the employee has properly recused from further work on the regulations as required by subpart F of this part, the employee may enter into employment discussions with the company and may accept the company's offer to pay for airfare, hotel, and meals in connection with an interview trip.

(4) Provided by a former employer to attend a reception or similar event when other former employees have been invited to attend, the invitation and benefits are based on the former employment relationship, and it is clear that such benefits have not been offered or enhanced because of the employee's official position.

Example 1 to paragraph (e)(4): An employee of the Department of the Army is invited by a former employer, an Army contractor, to attend its annual holiday dinner party. The former employer traditionally invites both its current and former employees to the holiday dinner regardless of their current employment activities. Under these circumstances, the employee may attend the dinner because the dinner

invitation is a result of the employee's former outside employment activities, other former employees have been asked to attend, and the gift is not offered because of the employee's official position.

(5) For purposes of paragraphs (e)(1) through (4) of this section, *employment* means any form of non-Federal employment or business relationship involving the provision of personal services.

(f) *Gifts in connection with political activities permitted by the Hatch Act Reform Amendments.* An employee who, in accordance with the Hatch Act Reform Amendments of 1993, at 5 U.S.C. 7323, may take an active part in political management or in political campaigns, may accept meals, lodgings, transportation, and other benefits, including free attendance at events, for the employee and an accompanying guest, when provided, in connection with such active participation, by a political organization described in 26 U.S.C. 527(e). Any other employees, such as a security officers, whose official duties require them to accompany an employee to a political event, may accept meals, free attendance, and entertainment provided at the event by such an organization.

Example 1 to paragraph (f): The Secretary of the Department of Health and Human Services may accept an airline ticket and hotel accommodations furnished by the campaign committee of a candidate for the United States Senate in order to give a speech in support of the candidate.

(g) *Gifts of free attendance at widely attended gatherings*—(1) *Authorization.* When authorized in writing by the agency designee pursuant to paragraph (g)(3) of this section, an employee may accept an unsolicited gift of free attendance at all or appropriate parts of a widely attended gathering. For an employee who is subject to a leave system, attendance at the event will be on the employee's own time or, if authorized by the employee's agency, on excused absence pursuant to applicable guidelines for granting such absence, or otherwise without charge to the employee's leave account.

(2) *Widely attended gatherings.* A gathering is widely attended if it is expected that:

(i) A large number of persons will attend;

(ii) Persons with a diversity of views or interests will be present, for example, if it is open to members from throughout the interested industry or profession or if those in attendance represent a range of persons interested in a given matter; and

(iii) There will be an opportunity to exchange ideas and views among invited persons.

(3) *Written authorization by the agency designee.* The agency designee may authorize an employee or employees to accept a gift of free attendance at all or appropriate parts of a widely attended gathering only if the agency designee issues a written determination after finding that:

(i) The event is a widely attended gathering, as set forth in paragraph (g)(2) of this section;

(ii) The employee's attendance at the event is in the agency's interest because it will further agency programs or operations;

(iii) The agency's interest in the employee's attendance outweighs the concern that the employee may be, or may appear to be, improperly influenced in the performance of official duties; and

(iv) If a person other than the sponsor of the event invites or designates the employee as the recipient of the gift of free attendance and bears the cost of that gift, the event is expected to be attended by more than 100 persons, and the value of the gift of free attendance does not exceed $480.

(4) *Determination of agency interest.* In determining whether the agency's interest in the employee's attendance outweighs the concern that the employee may be, or may appear to be, improperly influenced in the performance of official duties, the agency designee may consider relevant factors including:

(i) The importance of the event to the agency;

(ii) The nature and sensitivity of any pending matter affecting the interests of the person who extended the invitation and the significance of the employee's role in any such matter;

(iii) The purpose of the event;

(iv) The identity of other expected participants;

(v) Whether acceptance would reasonably create the appearance that the donor is receiving preferential treatment;

(vi) Whether the Government is also providing persons with views or interests that differ from those of the donor with access to the Government; and

(vii) The market value of the gift of free attendance.

(5) *Cost provided by person other than the sponsor of the event.* The cost of the employee's attendance will be considered to be provided by a person other than the sponsor of the event when such person designates the employee to be invited and bears the cost of the employee's attendance through a contribution or other payment intended to facilitate the employee's attendance. Payment of dues or a similar assessment to a sponsoring organization does not constitute a payment intended to facilitate a particular employee's attendance.

(6) *Accompanying guest.* When others in attendance will generally be accompanied by a guest of their choice, and when the invitation is from the same person who has invited the employee, the agency designee may authorize an employee to accept an unsolicited invitation of free attendance to one accompanying guest to participate in all or a portion of the event at which the employee's free attendance is permitted under paragraph (g)(1) of this section. The authorization required by this paragraph (g)(6) must be provided in writing.

Example 1 to paragraph (g): An aerospace industry association that is a prohibited source sponsors an industry-wide, two-day seminar for which it charges a fee of $800 and anticipates attendance of approximately 400. An Air Force contractor pays $4,000 to the association so that the association can extend free invitations to five Air Force officials designated by the contractor. The Air Force officials may not accept the gifts of free attendance because the contractor, rather than the association, provided the cost of their attendance; the contractor designated the specific employees to receive the gift of free attendance; and the value of the gift exceeds $480 per employee.

Example 2 to paragraph (g): An aerospace industry association that is a prohibited source sponsors an industry-wide, two-day seminar for which it charges a fee of $25 and anticipates attendance of approximately 50. An Air Force contractor pays $125 to the association so that the association can extend free invitations to five Air Force officials designated by the contractor. The Air Force officials may not accept the gifts of free attendance because the contractor, rather than the association, provided the cost of their attendance; the contractor designated the specific employees to receive the gift of free attendance; and the event was not expected to be attended by more than 100 persons.

Example 3 to paragraph (g): An aerospace industry association that is a prohibited source sponsors an industry-wide, two-day seminar for which it charges a fee of $800 and anticipates attendance of approximately 400. An Air Force contractor pays $4,000 in order that the association might invite any five Federal employees. An Air

Force official to whom the sponsoring association, rather than the contractor, extended one of the five invitations could attend if the employee's participation were determined to be in the interest of the agency and the employee received a written authorization.

Example 4 to paragraph (g): An employee of the Department of Transportation is invited by a news organization to an annual press dinner sponsored by an association of press organizations. Tickets for the event cost $480 per person and attendance is limited to 400 representatives of press organizations and their guests. If the employee's attendance is determined to be in the interest of the agency and the agency designee provides a written authorization, the employee may accept the invitation from the news organization because more than 100 persons will attend and the cost of the ticket does not exceed $480. However, if the invitation were extended to the employee and an accompanying guest, the employee's guest could not be authorized to attend for free because the market value of the gift of free attendance would exceed $480.

Example 5 to paragraph (g): An employee of the Department of Energy (DOE) and their spouse have been invited by a major utility executive to a small dinner party. A few other officials of the utility and their spouses or other guests are also invited, as is a representative of a consumer group concerned with utility rates and their spouse. The DOE official believes the dinner party will provide an opportunity to socialize with and get to know those in attendance. The employee may not accept the free invitation under this exception, even if attendance could be determined to be in the interest of the agency. The small dinner party is not a widely attended gathering. Nor could the employee be authorized to accept even if the event were instead a corporate banquet to which forty company officials and their spouses or other guests were invited. In this second case, notwithstanding the larger number of persons expected (as opposed to the small dinner party just noted) and despite the presence of the consumer group representative and spouse who are not officials of the utility, those in attendance would still not represent a diversity of views or interests. Thus, the company banquet would not qualify as a widely attended gathering under those circumstances either.

Example 6 to paragraph (g): An Assistant U.S. Attorney is invited to attend a luncheon meeting of a local bar association to hear a distinguished judge lecture on cross-examining expert witnesses. Although members of the bar association are assessed a $15 fee for the meeting, the Assistant U.S. Attorney may accept the bar association's offer to attend for free, even without a determination of agency interest. The gift can be accepted under the $20 gift exception at paragraph (a) of this section.

Example 7 to paragraph (g): An employee of the Department of the Interior authorized to speak on the first day of a four-day conference on endangered species may accept the sponsor's waiver of the conference fee for the first day of the conference under § 2635.203(b)(8). If the conference is widely attended, the employee may be authorized to accept the sponsor's offer to waive the attendance fee for the remainder of the conference if the agency designee has made a written determination that attendance is in the agency's interest.

Example 8 to paragraph (g): A military officer has been approved to attend a widely attended gathering, pursuant to paragraph (g) of this section, that will be held in the same city as the officer's duty station. The defense contractor sponsoring the event has offered to transport the officer in a limousine to the event. The officer may not accept the offer of transportation because the definition of *free attendance* set forth in § 2635.203(g) excludes travel, and the market value of the transportation would exceed $20.

(h) *Social invitations.* An employee may accept food, refreshments, and entertainment, not including travel or lodgings, for the employee and an accompanying guest, at a social event attended by several persons if:

(1) The invitation is unsolicited and is from a person who is not a prohibited source;

(2) No fee is charged to any person in attendance; and

(3) If either the sponsor of the event or the person extending the invitation to the employee is not an individual, the agency designee has made a written determination after finding that the employee's attendance would not cause a reasonable person with knowledge of the relevant facts to question the employee's integrity or impartiality, consistent with § 2635.201(b).

Example 1 to paragraph (h): An employee of the White House Press Office has been invited to a social dinner for current and former White House Press Officers at the home of an individual who is not a prohibited source. The employee may attend even if the invitation is because of the employee's official position.

(i) *Meals, refreshments, and entertainment in foreign areas.* An employee assigned to duty in, or on official travel to, a foreign area as defined in 41 CFR 300–3.1 may accept unsolicited food, refreshments, or entertainment in the course of a breakfast, luncheon, dinner, or other meeting or event provided:

(1) The market value in the foreign area of the food, refreshments, or entertainment provided at the meeting or event, as converted to U.S. dollars, does not exceed the per diem rate for the foreign area specified in the U.S. Department of State's Maximum Rates of Per Diem Allowances for Travel in Foreign Areas, Per Diem Supplement, section 925 to the Standardized Regulations (GC–FA), available at *www.state.gov;*

(2) There is participation in the meeting or event by non-U.S. citizens or by representatives of foreign governments or other foreign entities;

(3) Attendance at the meeting or event is part of the employee's official duties to obtain information, disseminate information, promote the export of U.S. goods and services, represent the United States, or otherwise further programs or operations of the agency or the U.S. mission in the foreign area; and

(4) The gift of meals, refreshments, or entertainment is from a person other than a foreign government as defined in 5 U.S.C. 7342(a)(2).

Example 1 to paragraph (i): A number of local business owners in a developing country are eager for a U.S. company to locate a manufacturing facility in their province. An official of the U.S. International Development Finance Corporation may accompany the visiting vice president of the U.S. company to a dinner meeting hosted by the business owners at a province restaurant when the market value of the food and refreshments does not exceed the per diem rate for that country.

(j) *Gifts to the President or Vice President.* Because of considerations relating to the conduct of their offices, including those of protocol and etiquette, the President or the Vice President may accept any gift on their own behalf or on behalf of any family member, provided that such acceptance does not violate § 2635.205(a) or (b), 18 U.S.C. 201(b) or 201(c)(3), or the Constitution of the United States.

(k) *Gifts authorized by supplemental agency regulation.* An employee may accept any gift when acceptance of the gift is specifically authorized by a supplemental agency regulation issued with the concurrence of the Office of

Government Ethics, pursuant to § 2635.105.

(l) *Gifts accepted under specific statutory authority.* The prohibitions on acceptance of gifts from outside sources contained in this subpart do not apply to any item which a statute specifically authorizes an employee to accept. Gifts which may be accepted by an employee under the authority of specific statutes include, but are not limited to:

(1) Free attendance, course or meeting materials, transportation, lodgings, food and refreshments, or reimbursements therefor incident to training or meetings when accepted by the employee under the authority of 5 U.S.C. 4111. The employee's acceptance must be approved by the agency in accordance with part 410 of this title; or

(2) Gifts from a foreign government or international or multinational organization, or its representative, when accepted by the employee under the authority of the Foreign Gifts and Decorations Act, 5 U.S.C. 7342. As a condition of acceptance, an employee must comply with requirements imposed by the agency's regulations or procedures implementing that Act.

(m) *Gifts of informational materials.* (1) An employee may accept unsolicited gifts of informational materials, provided that:

(i) The aggregate market value of all informational materials received from any one person does not exceed $100 in a calendar year; or

(ii) If the aggregate market value of all informational materials from the same person exceeds $100 in a calendar year, an agency designee has made a written determination after finding that acceptance by the employee would not be inconsistent with the standard set forth in § 2635.201(b).

(2) *Informational materials* are writings, recordings, documents, records, or other items that:

(i) Are educational or instructive in nature;

(ii) Are not primarily created for entertainment, display, or decoration; and

(iii) Contain information that relates in whole or in part to the following categories:

(A) The employee's official duties or position, profession, or field of study;

(B) A general subject matter area, industry, or economic sector affected by or involved in the programs or operations of the agency; or

(C) Another topic of interest to the agency or its mission.

Example 1 to paragraph (m): An analyst at the Agricultural Research Service receives an edition of an agricultural research journal in the mail from a consortium of private farming operations concerned with soil toxicity. The journal edition has a market value of $75. The analyst may accept the gift.

Example 2 to paragraph (m): An inspector at the Mine Safety and Health Administration receives a popular novel with a market value of $25 from a mine operator. Because the novel is primarily for entertainment purposes, the inspector may not accept the gift.

Example 3 to paragraph (m): An employee at the Department of the Army is offered an encyclopedia on cyberwarfare from a prohibited source. The cost of the encyclopedia is far in excess of $100. The agency designee determines that acceptance of the gift would be inconsistent with the standard set out in § 2635.201(b). The employee may not accept the gift under paragraph (m) of this section.

(n) *Legal expense funds and pro bono legal services.* An employee who seeks legal representation for a matter arising in connection with the employee's past or current official position, the employee's prior position on a campaign of a candidate for President or Vice President, or the employee's prior position on a Presidential Transition Team may accept:

(1) Payments for legal expenses paid out of a legal expense fund that is established and operated in accordance with subpart J of this part; and

(2) *Pro bono* legal services provided in accordance with subpart J of this part.

§ 2635.205 Limitations on use of exceptions.

Notwithstanding any exception provided in this subpart, other than § 2635.204(j), an employee may not:

(a) Accept a gift in return for being influenced in the performance of an official act;

(b) Use, or permit the use of, the employee's Government position, or any authority associated with public office, to solicit or coerce the offering of a gift;

(c) Accept gifts from the same or different sources on a basis so frequent that a reasonable person would be led to believe the employee is using the employee's public office for private gain;

Example 1 to paragraph (c): A purchasing agent for a Department of Veterans Affairs medical center routinely deals with representatives of pharmaceutical manufacturers who provide information about new company products. Because of a crowded calendar, the purchasing agent has offered to meet with manufacturer representatives during lunch hours Tuesdays through Thursdays, and the representatives routinely arrive at the employee's office bringing a sandwich and a soft drink for the employee. Even though the market value of each of the lunches is less than $6 and the aggregate value from any one manufacturer does not exceed the $50 aggregate limitation in § 2635.204(a) on gifts of $20 or less, the practice of accepting even these modest gifts on a recurring basis is improper.

(d) Accept a gift in violation of any statute; relevant statutes applicable to all employees include, but are not limited to:

(1) 18 U.S.C. 201(b), which prohibits public officials from, directly or indirectly, corruptly demanding, seeking, receiving, accepting, or agreeing to receive or accept anything of value personally or for any other person or entity in return for being influenced in the performance of an official act; being influenced to commit or aid in committing, or to collude in, or allow, any fraud, or make opportunity for the commission of any fraud, on the United States; or for being induced to do or omit to do any action in violation of their official duties. As used in 18 U.S.C. 201(b), the term ''public official'' is broadly construed and includes regular and special Government employees as well as all other Government officials; and

(2) 18 U.S.C. 209, which prohibits employees, other than special Government employees, from receiving any salary or any contribution to or supplementation of salary from any source other than the United States as compensation for services as a Government employee. The statute contains several specific exceptions to this general prohibition, including an exception for contributions made from the treasury of a State, county, or municipality;

(e) Accept a gift in violation of any Executive order; or

(f) Accept any gift when acceptance of the gift is specifically prohibited by a supplemental agency regulation issued with the concurrence of the Office of Government Ethics, pursuant to § 2635.105.

§ 2635.206 Proper disposition of prohibited gifts.

(a) Unless a gift is accepted by an agency acting under specific statutory authority, an employee who has received a gift that cannot be accepted under this subpart must dispose of the gift in accordance with the procedures set forth in this section. The employee must promptly complete the authorized disposition of the gift. The obligation to dispose of a gift that cannot be accepted under this subpart is independent of an

agency's decision regarding corrective or disciplinary action under § 2635.106.

(1) *Gifts of tangible items.* The employee must promptly return any tangible item to the donor or pay the donor its market value; or, in the case of a tangible item with a market value of $100 or less, the employee may destroy the item. An employee who cannot ascertain the actual market value of an item may estimate its market value by reference to the retail cost of similar items of like quality.

Example 1 to paragraph (a)(1): A Department of Commerce employee received a $25 T-shirt from a prohibited source after providing training at a conference. Because the gift would not be permissible under an exception to this subpart, the employee must either return or destroy the T-shirt or promptly reimburse the donor $25. Destruction may be carried out by physical destruction or by permanently discarding the T-shirt by placing it in the trash.

Example 2 to paragraph (a)(1): To avoid public embarrassment to the seminar sponsor, an employee of the National Park Service did not decline a barometer worth $200 given at the conclusion of a speech on Federal lands policy. To comply with this section, the employee must either promptly return the barometer or pay the donor the market value of the gift. Alternatively, the National Park Service may choose to accept the gift if permitted under specific statutory gift acceptance authority. The employee may not destroy this gift, as the market value is in excess of $100.

(2) *Gifts of perishable items.* When it is not practical to return a tangible item in accordance with paragraph (a)(1) of this section because the item is perishable, the employee may, at the discretion of the employee's supervisor or the agency designee, give the item to an appropriate charity, share the item within the recipient's office, or destroy the item.

Example 1 to paragraph (a)(2): With approval by the recipient's supervisor, a floral arrangement sent by a disability claimant to a helpful employee of the Social Security Administration may be placed in the office's reception area.

(3) *Gifts of intangibles.* The employee must promptly reimburse the donor the market value for any entertainment, favor, service, benefit, or other intangible. Subsequent reciprocation by the employee does not constitute reimbursement.

Example 1 to paragraph (a)(3): A Department of Defense employee wishes to attend a charitable event for which they were offered a $300 ticket by a prohibited source. Although attendance is not in the interest of the agency under § 2635.204(g), the employee may attend if they reimburse the donor the $300 face value of the ticket.

(4) *Gifts from foreign governments or international organizations.* The employee must dispose of gifts from foreign governments or international organizations in accordance with 41 CFR part 102–42.

(b) An agency may authorize disposition or return of gifts at Government expense. Employees may use penalty mail to forward reimbursements required or permitted by this section.

(c) Employees who, on their own initiative, promptly comply with the requirements of this section will not be deemed to have improperly accepted an unsolicited gift. Employees who promptly consult their agency ethics official to determine whether acceptance of an unsolicited gift is proper and who, upon the advice of the ethics official, return the gift or otherwise dispose of the gift in accordance with this section, will be considered to have complied with the requirements of this section on the employee's own initiative.

(d) Employees are encouraged to record any actions they have taken to properly dispose of gifts that cannot be accepted under this subpart, such as by sending an electronic mail message to the appropriate agency ethics official or the employee's supervisor.

Subpart C—Gifts Between Employees

§ 2635.301 Overview.

This subpart contains standards that prohibit an employee from giving or contributing to a gift to an official superior, and official superiors are prohibited from knowingly accepting such a gift. Employees also are prohibited from soliciting a contribution from another employee for a gift to an official superior. In addition, employees are prohibited from accepting a gift from an employee who receives less pay. The prohibitions in this subpart apply unless the item is excluded from the definition of a *gift* (see § 2635.303(a)) or falls within one of the exceptions set forth in this subpart. Gifts from outside sources are subject to the limitations set forth in subpart B of this part.

§ 2635.302 General standards.

(a) *Gifts to superiors.* Except as provided in this subpart, employees may not:

(1) Directly or indirectly, give a gift to or make a contribution toward a gift for an official superior, and an official superior may not knowingly accept such a gift; or

(2) Solicit a contribution from another employee for a gift to either their own or the other employee's official superior.

(b) *Gifts from employees receiving less pay.* Except as provided in this subpart, employees may not, directly or indirectly, accept a gift from an employee who receives less pay unless:

(1) There is a personal relationship between the two employees that would justify the gift and the employee receiving the gift is not the official superior of the employee giving the gift; or

(2) The employee giving the gift is the official superior of the employee receiving the gift.

Example 1 to paragraph (b): A GS–13 Department of Homeland Security (DHS) employee has been close personal friends with a neighbor, a GS–15 employee in another government agency, for many years. During their friendship, the GS–13 employee has often allowed the neighbor's family to use their vacation house rent-free. The GS–15 employee recently accepted a position at DHS, and in the new position will be the direct supervisor of the GS–13 employee. Although the personal relationship between the two employees justified the gift of rent-free use of the vacation home before they were both employed at DHS, for the duration of their supervisor-subordinate relationship the GS–13 employee may not allow the GS–15 neighbor to use the vacation house rent-free or give other gifts, except as permitted by the exceptions contained in this subpart.

(c) *Limitation on use of exceptions.* Notwithstanding any exception provided in this subpart, an official superior may not coerce the offering of a gift from a subordinate.

§ 2635.303 Definitions.

For purposes of this subpart, the following definitions apply:

(a) *Gift* has the meaning set forth in § 2635.203(b). For purposes of § 2635.203(b) and this paragraph (a) an employee will be deemed to have paid market value for any benefit received as a result of participating in a carpool or other such mutual arrangement between employees if the employee bears a fair proportion of the expense or effort involved.

(b) *Indirectly,* for purposes of § 2635.302(b), has the meaning set forth in § 2635.203(f). For purposes of § 2635.302(a), it includes a gift:

(1) Given with the employee's knowledge and acquiescence by the employee's parent, sibling, spouse, child, or dependent relative; or

(2) Given by a person other than the employee when circumstances indicate that the employee has promised or agreed to reimburse that person or to give that person something of value in exchange for giving the gift.

(c) *Market value* has the meaning set forth in § 2635.203(c), subject to paragraph (a) of this section.

(d) *Official superior* means any other employee, other than the President and the Vice President, including but not limited to an immediate supervisor, whose official responsibilities include directing or evaluating the performance of the employee's official duties or those of any other official superior of the employee. For purposes of this subpart, employees are considered to be the subordinates of any of their official superiors.

(e) *Solicit* means to request contributions by personal communication or by general announcement.

(f) *Voluntary contribution* means a contribution given freely, without pressure or coercion. A contribution is not voluntary unless it is made in an amount determined by the contributing employee, except that when an amount for a gift is included in the cost for a luncheon, reception, or similar event, an employee who freely chooses to pay a proportionate share of the total cost in order to attend will be deemed to have made a voluntary contribution. Except in the case of contributions for a gift included in the cost of a luncheon, reception, or similar event, a statement that an employee may choose to contribute less or not at all must accompany any recommendation of an amount to be contributed for a gift to an official superior.

Example 1 to paragraph (f): A supervisory employee of the Agency for International Development has just been reassigned from Washington, DC, to a foreign duty location. As a farewell party, 12 subordinates have decided to take the supervisory employee out to lunch at a restaurant. It is understood that the employees will pay for their own meals and that the cost of the supervisor's lunch will be divided equally among the 12. Even though the amount they will contribute is not determined until the supervisor orders lunch, the contribution made by those who choose to participate in the farewell lunch is voluntary.

§ 2635.304 Exceptions.

The prohibitions set forth in § 2635.302(a) and (b) do not apply to a gift given or accepted under the circumstances described in paragraph (a) or (b) of this section. A contribution or the solicitation of a contribution that would otherwise violate the prohibitions set forth in § 2635.302(a) and (b) may only be made in accordance with paragraph (c) of this section.

(a) *General exceptions.* On an occasional basis, including any occasion on which gifts are traditionally given or exchanged, the following may be given to an official superior or accepted from a subordinate or an employee receiving less pay:

(1) Items, other than cash, with an aggregate market value of $10 or less per occasion;

(2) Items such as food and refreshments to be shared in the office among several employees;

(3) Personal hospitality provided at a residence which is of a type and value customarily provided by the employee to personal friends;

(4) Items given in connection with the receipt of personal hospitality if of a type and value customarily given on such occasions; and

(5) Unless obtained in violation of § 630.912 of this title, leave transferred under subpart I of part 630 of this title to an employee who is not an immediate supervisor.

Example 1 to paragraph (a): Upon returning to work following a vacation at the beach, a claims examiner with the Department of Veterans Affairs may give their supervisor, and the supervisor may accept, a bag of saltwater taffy purchased on the boardwalk for $8.

Example 2 to paragraph (a): An employee of the Federal Deposit Insurance Corporation whose bank examination responsibilities require frequent travel may not bring their supervisor, and the supervisor may not accept, souvenir coffee mugs from each of the cities the employee visits in the course of performing examination duties, even though each of the mugs costs less than $5. Gifts given on this basis are not occasional.

Example 3 to paragraph (a): The Secretary of Labor has invited the agency's General Counsel to a home dinner party. The General Counsel may bring a $15 bottle of wine to the dinner party and the Secretary may accept this customary gift from the subordinate, even though its cost is in excess of $10.

Example 4 to paragraph (a): For the holidays, an assistant may give their supervisor, and the supervisor may accept, a small succulent plant purchased for $10 or less. The assistant may also invite the supervisor to a New Year's Eve party in their home and the supervisor may attend.

(b) *Special, infrequent occasions.* A gift appropriate to the occasion may be given to an official superior or accepted from a subordinate or other employee receiving less pay:

(1) In recognition of infrequently occurring occasions of personal significance such as marriage, illness, bereavement, or the birth or adoption of a child; or

(2) Upon occasions that terminate a subordinate-official superior relationship, such as retirement, resignation, or transfer.

Example 1 to paragraph (b): The administrative assistant to the personnel director of the Tennessee Valley Authority may send a $30 floral arrangement to the personnel director who is in the hospital recovering from surgery. The personnel director may accept the gift.

Example 2 to paragraph (b): A chemist employed by the Food and Drug Administration has been invited to the wedding of the lab director who is an official superior. The chemist may give the lab director and the lab director's spouse, and the couple may accept, a place setting in the couple's selected china pattern purchased for $70.

Example 3 to paragraph (b): Upon the occasion of the supervisor's retirement from Federal service, an employee of the Fish and Wildlife Service may give the supervisor a book of wildlife photographs purchased for $19. The retiring supervisor may accept the book.

Example 4 to paragraph (b): An economist at the Consumer Financial Protection Bureau overhears their supervisor talking about their upcoming 50th birthday. Although a 50th birthday may be conventionally seen as a unique ''milestone'' worthy of additional celebration, the employee may not give their supervisor a $25 bottle of wine as a present because a birthday is not an infrequently occurring occasion.

(c) *Voluntary contributions.* (1) An employee may solicit voluntary contributions of nominal amounts from fellow employees for an appropriate gift to an official superior and an employee may make a voluntary contribution of a nominal amount to an appropriate gift to an official superior:

(i) On a special, infrequent occasion as described in paragraph (b) of this section; or

(ii) On an occasional basis, for items such as food and refreshments to be shared in the office among several employees.

(2) An employee may accept such gifts to which a subordinate or an employee receiving less pay has voluntarily contributed pursuant to paragraph (c)(1) of this section.

Example 1 to paragraph (c): To mark the occasion of retirement, members of the immediate staff of the Under

Secretary of the Army would like to throw a party and provide the Under Secretary with a gift certificate. They may distribute an announcement of the party and list a nominal amount for a retirement gift as a suggested voluntary contribution for the party.

Example 2 to paragraph (c): An employee of the National Endowment for the Arts may not collect contributions for a Christmas gift for the Chairman. Christmas occurs annually and is not an occasion of personal significance.

Example 3 to paragraph (c): Subordinates may not take up a collection for a gift to an official superior on the occasion of the superior's swearing in or promotion to a higher-grade position within the supervisory chain of that organization. These are not events that mark the termination of the subordinate-official superior relationship, nor are they events of personal significance within the meaning of paragraph (b) of this section. However, subordinates may take up a collection and employees may contribute a nominal amount to buy refreshments to be consumed by everyone in the immediate office to mark either such occasion.

Example 4 to paragraph (c): Subordinates may each contribute a nominal amount to a fund to give a gift to an official superior upon the occasion of that superior's transfer or promotion to a position outside the organization.

Example 5 to paragraph (c): An Assistant Secretary at the Department of the Interior is getting married. The Assistant Secretary's assistant has decided that a microwave oven would be a nice gift from the staff and has informed each of the Assistant Secretary's subordinates that they should contribute $5 for the gift. The assistant's method of collection is improper. Although it is permissible to recommend a $5 contribution, the recommendation must be coupled with a statement that the employee whose contribution is solicited is free to contribute less or nothing at all.

§ 2635.305 Disposition of prohibited gifts.

Section 2635.206(a)(1) through (3) may be referenced when determining an appropriate disposition of a gift that may not be accepted under this subpart.

Subpart D—Conflicting Financial Interests

§ 2635.401 Overview.

Part 2640 of this chapter interprets and is the implementing regulation for 18 U.S.C. 208. This subpart summarizes the relevant statutory restrictions and some of the regulatory guidance found there. Specifically, this subpart contains two provisions relating to financial interests. One is a recusal requirement and the other is a prohibition on acquiring or continuing to hold specific financial interests. An employee may acquire or hold any financial interest not prohibited by § 2635.403. Notwithstanding that the acquisition or holding of a particular interest is proper, an employee is prohibited in accordance with § 2635.402 from participating in an official capacity in any particular matter in which, to the employee's knowledge, the employee or any person whose interests are imputed to the employee has a financial interest, if the particular matter will have a direct and predictable effect on that interest.

§ 2635.402 Disqualifying financial interests.

(a) *Statutory prohibition.* An employee is prohibited by criminal statute, 18 U.S.C. 208(a), from participating personally and substantially in an official capacity in any particular matter in which, to the employee's knowledge, the employee or any person whose interests are imputed to the employee under this statute has a financial interest, if the particular matter will have a direct and predictable effect on that interest.

Note 1 to paragraph (a): Standards applicable when seeking non-Federal employment are contained in subpart F of this part and, if followed, will ensure that an employee does not violate 18 U.S.C. 208(a) or this section when the employee is negotiating for or has an arrangement concerning future employment. In all other cases when the employee's participation would violate 18 U.S.C. 208(a), an employee must recuse from participating in the particular matter in accordance with paragraph (c) of this section or obtain a waiver or determine that an exemption applies, as described in paragraph (d) of this section.

(b) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Direct and predictable effect.* (i) A particular matter will have a direct effect on a financial interest if there is a close causal link between any decision or action to be taken in the matter and any expected effect of the matter on the financial interest. An effect may be direct even though it does not occur immediately. A particular matter will not have a direct effect on a financial interest, however, if the chain of causation is attenuated or is contingent upon the occurrence of events that are speculative or that are independent of, and unrelated to, the matter. A particular matter that has an effect on a financial interest only as a consequence of its effects on the general economy does not have a direct effect within the meaning of this subpart.

(ii) A particular matter will have a predictable effect if there is a real, as opposed to a speculative possibility that the matter will affect the financial interest. It is not necessary, however, that the magnitude of the gain or loss be known, and the dollar amount of the gain or loss is immaterial.

Note 2 to paragraph (b)(1): If a particular matter involves a specific party or parties, generally the matter will at most only have a direct and predictable effect, for purposes of this subpart, on a financial interest of the employee in or with a party, such as the employee's interest by virtue of owning stock. There may, however, be some situations in which, under the standards of this paragraph (b)(1), a particular matter will have a direct and predictable effect on an employee's financial interests in or with a nonparty. For example, if a party is a corporation, a particular matter may also have a direct and predictable effect on an employee's financial interests through ownership of stock in an affiliate, parent, or subsidiary of that party. Similarly, the disposition of a protest against the award of a contract to a particular company may also have a direct and predictable effect on an employee's financial interest in another company listed as a subcontractor in the proposal of one of the competing offerors.

Example 1 to paragraph (b)(1): An employee of the National Library of Medicine at the National Institutes of Health has just been asked to serve on the technical evaluation panel to review proposals for a new library computer search system. DEF Computer Corporation, a closely held company in which the employee and their spouse own a majority of the stock, has submitted a proposal. Because award of the systems contract to DEF or to any other offeror will have a direct and predictable effect on the financial interests of both the employee and the spouse, the employee cannot participate on the technical evaluation team unless this disqualification has been waived.

Example 2 to paragraph (b)(1): Upon assignment to the technical evaluation panel, the employee in example 1 to this paragraph (b)(1) finds that DEF Computer Corporation has not submitted a proposal. Rather, LMN Corp., with which DEF competes for private sector business, is one of the six offerors. The employee need not recuse from serving on the technical evaluation panel. Any effect on the employee's financial interests as a result of the agency's decision to award or not award the systems contract to LMN would be at most indirect and speculative.

(2) *Imputed interests.* For purposes of 18 U.S.C. 208(a) and this subpart, the financial interests of the following

persons will require the recusal of an employee to the same extent as if they were the employee's own interests:

(i) The employee's spouse;

(ii) The employee's minor child;

(iii) The employee's general partner;

(iv) An organization or entity which the employee serves as officer, director, trustee, general partner, or employee; and

(v) A person with whom the employee is negotiating for or has an arrangement concerning prospective employment. (Employees who are seeking other employment should refer to and comply with the standards in subpart F of this part.)

Example 1 to paragraph (b)(2): An employee of the Department of Education serves without compensation on the board of directors of Kinder World, Inc., a nonprofit corporation that engages in good works. Even though the employee's personal financial interests will not be affected, the employee must recuse from participating in the review of a grant application submitted by Kinder World. Award or denial of the grant will affect the financial interests of Kinder World and its financial interests are imputed to the employee as a member of its board of directors.

Example 2 to paragraph (b)(2): The spouse of an employee of the Food and Drug Administration has obtained a position with a well-established biomedical research company. The company has developed an artificial limb for which it is seeking FDA approval and the employee would ordinarily be asked to participate in the FDA's review and approval process. The spouse is a salaried employee of the company and has no stock or other direct or indirect ownership interest in the company. The spouse's position with the company is such that the granting or withholding of FDA approval will not have a direct and predictable effect on their salary or continued employment with the company. Because the FDA approval process will not affect the spouse's financial interests, this section does not require the employee to recuse from participating in that process. Nevertheless, because the impartiality principle is implicated as a result of the employee's covered relationship with the spouse's employer, as identified at § 2635.502(b)(1)(iii), the employee must follow the procedures established in § 2635.502 before participating in the FDA's review and approval process.

(3) *Particular matter.* The term particular matter encompasses only matters that involve deliberation, decision, or action that is focused upon the interests of specific persons, or a discrete and identifiable class of persons. Such a matter is covered by this subpart even if it does not involve formal parties and may include governmental action such as legislation or policy-making that is narrowly focused on the interests of such a discrete and identifiable class of persons. The term particular matter, however, does not extend to the consideration or adoption of broad policy options that are directed to the interests of a large and diverse group of persons. The particular matters covered by this subpart include a judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, or arrest.

Example 1 to paragraph (b)(3): The Internal Revenue Service's amendment of its regulations to change the manner in which depreciation is calculated is not a particular matter, nor is the Social Security Administration's consideration of changes to its appeal procedures for disability claimants.

Example 2 to paragraph (b)(3): Consideration by the Surface Transportation Board of regulations establishing safety standards for trucks on interstate highways involves a particular matter.

(4) *Personal and substantial.* To participate personally means to participate directly. It includes the direct and active supervision of the participation of a subordinate in the matter. To participate substantially means that the employee's involvement is of significance to the matter. Participation may be substantial even though it is not determinative of the outcome of a particular matter. However, it requires more than official responsibility, knowledge, perfunctory involvement, or involvement on an administrative or peripheral issue. A finding of substantiality should be based not only on the effort devoted to a matter, but also on the importance of the effort. While a series of peripheral involvements may be insubstantial, the single act of approving or participating in a critical step may be substantial. Personal and substantial participation may occur when, for example, an employee participates through decision, approval, disapproval, recommendation, investigation, or the rendering of advice in a particular matter.

(c) *Recusal.* Unless the employee is authorized to participate in the particular matter by virtue of a waiver or exemption described in paragraph (d) of this section or because the interest has been divested in accordance with paragraph (e) of this section, an employee must recuse from participating in a particular matter in which, to the employee's knowledge, the employee or a person whose interests are imputed to the employee has a financial interest, if the particular matter will have a direct and predictable effect on that interest. Recusal is accomplished by not participating in the particular matter.

(1) *Notification.* Employees who become aware of the need to recuse from participating in a particular matter to which they have been assigned must take whatever steps are necessary to ensure that they do not participate in the matter. Appropriate oral or written notification of their recusal may be made to an agency ethics official, coworkers, or a supervisor to document and help effectuate the recusal. Public filers as defined in subpart F of this part must comply with additional notification requirements set forth in § 2635.607 regarding negotiations for or agreement of future employment or compensation.

(2) *Documentation.* Employees need not file written recusal statements unless they are required by part 2634 of this chapter to file written evidence of compliance with an ethics agreement with the Office of Government Ethics or a designated agency ethics official, or are specifically directed by an agency ethics official or the person responsible for their assignments to file written recusal statements. However, it is often prudent for employees to create a record of their actions by providing written notice to an agency ethics official, a supervisor, or other appropriate official. In addition, public filers as defined in subpart F of this part must comply with the documentation requirements set forth in § 2635.607 regarding negotiations for or agreement of future employment or compensation.

Example 1 to paragraph (c): An Assistant Secretary of the Department of the Interior owns recreational property that borders on land which is being considered for annexation to a national park. Annexation would directly and predictably increase the value of the Assistant Secretary's vacation property and, thus, the Assistant Secretary must recuse from participating in any way in the Department's deliberations or decisions regarding the annexation. Because the Assistant Secretary is responsible for determining their own work assignments, they may accomplish their recusal merely by ensuring that they do not participate in the particular matter. Because of the level of their position, however, the Assistant Secretary might be wise to establish a record that they have acted properly by providing a written recusal statement to

an official superior and by providing written notification of the recusal to subordinates to ensure that they do not raise or discuss any issues related to the annexation with the Assistant Secretary.

(d) *Waiver of or exemptions from recusal requirement.* An employee who would otherwise be required to recuse under 18 U.S.C. 208(a) may be permitted to participate in a particular matter if the financial interest that would otherwise require recusal is the subject of a regulatory exemption or individual waiver described in this paragraph (d), or results from certain Indian birthrights as described in 18 U.S.C. 208(b)(4).

(1) *Regulatory exemptions.* Under 18 U.S.C. 208(b)(2), regulatory exemptions of general applicability have been issued by the Office of Government Ethics, based on its determination that particular interests are too remote or too inconsequential to affect the integrity of the services of employees to whom those exemptions apply. See part 2640, subpart B of this chapter.

(2) *Individual waivers.* An individual waiver enabling the employee to participate in one or more particular matters may be issued under 18 U.S.C. 208(b)(1) if, in advance of the employee's participation:

(i) The employee:

(A) Advises the Government official responsible for the employee's appointment (or other Government official to whom authority to issue such a waiver for the employee has been delegated) about the nature and circumstances of the particular matter or matters; and

(B) Makes full disclosure to such official of the nature and extent of the relevant financial interest; and

(ii) Such official determines, in writing, that the employee's financial interest in the particular matter or matters is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from such employee. See part 2640, subpart C of this chapter (providing additional guidance).

(3) *Federal advisory committee member waivers.* An individual waiver may be issued under 18 U.S.C. 208(b)(3) to a special Government employee serving on, or under consideration for appointment to, an advisory committee within the meaning of the Federal Advisory Committee Act if the Government official responsible for the employee's appointment (or other Government official to whom authority to issue such a waiver for the employee has been delegated):

(i) Reviews the financial disclosure report filed by the special Government employee pursuant to 5 U.S.C. chapter 131; and

(ii) Certifies in writing that the need for the individual's services outweighs the potential for a conflict of interest created by the relevant financial interest. See part 2640, subpart C, of this chapter (providing additional guidance).

(4) *Consultation and notification regarding waivers.* When practicable, an official is required to consult formally or informally with the Office of Government Ethics prior to granting a waiver referred to in paragraph (d)(2) or (3) of this section. A copy of each such waiver is to be forwarded to the Director of the Office of Government Ethics.

(e) *Divestiture of a disqualifying financial interest.* Upon sale or other divestiture of the asset or other interest that would otherwise require the employee to recuse from participating in a particular matter, 18 U.S.C. 208(a) and paragraph (c) of this section will no longer prohibit the employee's participation in the matter.

(1) *Voluntary divestiture.* An employee who would otherwise be required to recuse from participating in a particular matter may voluntarily sell or otherwise divest the interest that create the recusal requirement.

(2) *Directed divestiture.* An employee may be required to sell or otherwise divest the disqualifying financial interest if the continued holding of that interest is prohibited by statute or by agency supplemental regulation issued in accordance with § 2635.403(a), or if the agency determines in accordance with § 2635.403(b) that a substantial conflict exists between the financial interest and the employee's duties or accomplishment of the agency's mission.

(3) *Eligibility for special tax treatment.* An employee who is directed to divest an interest may be eligible to defer the tax consequences of divestiture under part 2634, subpart J, of this chapter. An employee who divests before obtaining a certificate of divestiture will not be eligible for this special tax treatment.

(f) *Official duties that give rise to potential conflicts.* When their official duties create a substantial likelihood that they may be assigned to a particular matter from which they would be required to recuse, employees should advise their supervisors or other persons responsible for their assignments of that potential so that conflicting assignments can be avoided, consistent with the agency's needs.

§ 2635.403 Prohibited financial interests.

An employee may not acquire or hold any financial interest that agency employees are prohibited from acquiring or holding by statute, by agency regulation issued in accordance with paragraph (a) of this section, or by reason of an agency determination of substantial conflict under paragraph (b) of this section.

(a) *Agency regulation prohibiting certain financial interests.* An agency may, by supplemental agency regulation, prohibit or restrict the acquisition or holding of a financial interest or a class of financial interests by agency employees, or any category of agency employees, and the spouses and minor children of those employees, based on the agency's determination that the acquisition or holding of such financial interests would cause a reasonable person to question the impartiality and objectivity with which agency programs are administered. When the agency restricts or prohibits the holding of certain financial interests by its employees' spouses or minor children, any such prohibition or restriction must be based on a determination that there is a direct and appropriate nexus between the prohibition or restriction as applied to spouses and minor children and the efficiency of the service.

Note 1 to paragraph (a): There is no statute of Governmentwide applicability prohibiting employees from holding or acquiring any financial interest. Statutory restrictions, if any, are contained in agency statutes which, in some cases, may be implemented by agency regulations issued independent of this part.

(b) *Agency determination of substantial conflict.* An agency may prohibit or restrict an individual employee from acquiring or holding a financial interest or a class of financial interests based upon the agency designee's determination that the holding of such interest or interests will:

(1) Require the employee to recuse from particular matters so central or critical to the performance of the employee's official duties that their ability to perform the duties of their position would be materially impaired; or

(2) Adversely affect the efficient accomplishment of the agency's mission because another employee cannot be readily assigned to perform work from which the employee would be recused by reason of the financial interest.

Example 1 to paragraph (b): An Air Force employee who owns $33,778 of stock in a major aircraft engine manufacturer is being considered for promotion to a position that involves responsibility for development of a new fighter airplane. If the agency determined that engineering and other

decisions about the Air Force's requirements for the fighter would directly and predictably affect the employee's financial interests, the employee could not, by virtue of 18 U.S.C. 208(a), perform these significant duties of the position while retaining stock in the company. The agency can require the employee to sell the stock as a condition of being selected for the position rather than allowing the employee to recuse from particular matters.

(c) *Definition of financial interest.* For purposes of this section:

(1) Except as provided in paragraph (c)(2) of this section, the term financial interest is limited to financial interests that are owned by the employee or by the employee's spouse or minor children. However, the term is not limited to only those financial interests that would require the employee to recuse under 18 U.S.C. 208(a) and § 2635.402. The term includes any current or contingent ownership, equity, or security interest in real or personal property or a business, and may include an indebtedness or compensated employment relationship. It thus includes, for example, interests in the nature of stocks, bonds, partnership interests, fee and leasehold interests, mineral and other property rights, deeds of trust, and liens, and extends to any right to purchase or acquire any such interest, such as a stock option or commodity future. It does not include a future interest created by someone other than the employee, the employee's spouse, or minor child, or any right as a beneficiary of an estate that has not been settled.

Example 1 to paragraph (c)(1): A regulatory agency has concluded that ownership by its employees of stock in entities regulated by the agency would significantly diminish public confidence in the agency's performance of its regulatory functions and thereby interfere with the accomplishment of its mission. In its supplemental agency regulations, the agency may prohibit its employees from acquiring or continuing to hold stock in regulated entities.

Example 2 to paragraph (c)(1): An agency that insures bank deposits may, by supplemental agency regulation, prohibit its employees who are bank examiners from obtaining loans from banks they examine. Examination of a member bank could have no effect on an employee's fixed obligation to repay a loan from that bank and, thus, would not affect an employee's financial interests so as to require recusal under § 2635.402. Nevertheless, a loan from a member bank is a discrete financial interest within the meaning of paragraph (c) of this section that may, when appropriate, be prohibited by supplemental agency regulation.

(2) The term financial interest includes service, with or without compensation, as an officer, director, trustee, general partner, or employee of any person, including a nonprofit entity, whose financial interests are imputed to the employee under § 2635.402(b)(2)(iii) or (iv).

Example 1 to paragraph (c)(2): The Foundation for the Preservation of Wild Horses maintains herds of horses that graze on public and private lands. Because its costs are affected by Federal policies regarding grazing permits, the Foundation routinely comments on all proposed rules governing use of Federal grasslands issued by the Bureau of Land Management (BLM). BLM may require an employee to resign from their uncompensated position as Vice President of the Foundation as a condition of a promotion to a policy-level position within the Bureau rather than allowing the employee to rely on recusal in particular cases.

(d) *Reasonable period to divest or terminate.* Whenever an agency directs divestiture of a financial interest under paragraph (a) or (b) of this section, the employee will be given a reasonable period of time, considering the nature of their particular duties and the nature and marketability of the interest, within which to comply with the agency's direction. Except in cases of unusual hardship, as determined by the agency, a reasonable period must not exceed 90 days from the date divestiture is first directed. However, as long as the employee continues to hold the financial interest, all restrictions imposed by this subpart remain applicable.

(e) *Eligibility for special tax treatment.* Employees required to sell or otherwise divest a financial interest may be eligible to defer the tax consequences of divestiture under part 2634, subpart J, of this chapter.

Subpart E—Impartiality in Performing Official Duties

§ 2635.501 Overview.

(a) *Scope.* This subpart is intended to ensure that employees take appropriate steps to avoid an appearance of loss of impartiality in the performance of their official duties in circumstances other than those covered by the criminal conflict of interest statute, 18 U.S.C. 208(a).

(1) The provisions of § 2635.502 are designed to help employees identify and take appropriate steps regarding their participation in particular matters involving specific parties that may cause a reasonable person with knowledge of the relevant facts to question their impartiality. Employees and agencies should analyze such appearance issues, and employees may receive authorization to participate in such matters, using the procedures in this subpart.

(2) Under § 2635.503, an employee who has received a covered payment from a former employer is subject, in the absence of a waiver pursuant to § 2635.503(c), to a two-year period of recusal from participating in particular matters in which that former employer is or represents a party.

(3) An employee is prohibited by 18 U.S.C. 208(a) from participating personally and substantially in an official capacity in any particular matter in which, to the employee's knowledge, the employee has a personal or imputed financial interest, if the particular matter will have a direct and predictable effect on that interest. Section 208(a), its interpreting and implementing regulations under part 2640 of this chapter, and the regulations at subparts D and F of this part, apply when the particular matter would affect the financial interests of one of these persons.

(b) *Distinction between authorizations under this subpart and waivers and exemptions under the criminal conflict of interest law.* (1) When an employee's participation in a particular matter involving specific parties would raise a question in the mind of a reasonable person about the employee's impartiality, but would not violate 18 U.S.C. 208(a), the agency designee may make a determination, as explained in § 2635.502(d), and authorize the employee to participate in the matter.

(2) When the employee's participation in a particular matter would affect any one of the financial interests described in 18 U.S.C. 208(a), only a statutory waiver or exemption, as described in §§ 2635.402(d) and 2635.605(a), will enable the employee to participate in that matter. The specific requirements for regulatory exemptions and statutory waivers are contained in part 2640, subparts B and C, of this chapter.

(3) An applicable waiver or exemption under part 2640 of this chapter also authorizes an employee's participation in particular matters that would otherwise be restricted by § 2635.502. Specifically, if an employee meets all prerequisites for the application of one of the regulatory exemptions set forth in part 2640, subpart B, of this chapter, that constitutes a determination that the interest of the Government in the

employee's participation in a particular matter outweighs the concern that a reasonable person may question the integrity of agency programs and operations. Similarly, if the employee complies with all terms of a statutory waiver granted pursuant to part 2640, subpart C, of this chapter, that also constitutes a determination that the interest of the Government in the employee's participation in a particular matter outweighs the concern that a reasonable person may question the integrity of agency programs and operations. In such cases, the employee is not required to recuse under § 2635.502(e) or request authorization to participate under § 2635.502(d).

Note 1 to § 2635.501: Even if the employee or agency designee determines that this subpart is not applicable, the employee's supervisor or other individuals responsible for assigning work to the employee may decide not to assign certain work to the employee for other reasons, including to address appearance and impartiality concerns not covered by this subpart.

§ 2635.502 Personal and business relationships.

(a) *Consideration of appearances by the employee.* In considering whether any of the following would cause a reasonable person to question their impartiality, employees may seek the assistance of their supervisor, an agency ethics official, or the agency designee.

(1) When an employee knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interest of a member of the employee's household, and the employee determines that the circumstances would cause a reasonable person with knowledge of the relevant facts to question the employee's impartiality in the matter, the employee should not participate in the matter unless the employee has received a determination from the agency designee regarding the appearance problem in accordance with paragraph (c) of this section or received an authorization from the agency designee in accordance with paragraph (d) of this section.

(2) When an employee knows that a person with whom the employee has a covered relationship is or represents a party to a particular matter involving specific parties, and the employee determines that the circumstances would cause a reasonable person with knowledge of the relevant facts to question their impartiality in the matter, the employee should not participate in the matter unless the employee has received a determination from the agency designee regarding the appearance problem in accordance with paragraph (c) of this section or received an authorization from the agency designee in accordance with paragraph (d) of this section.

(3) Employees who are concerned that circumstances other than those specifically described in paragraphs (a)(1) and (2) of this section would raise a question regarding their impartiality should use the process described in this section to determine whether they should not participate in a particular matter.

(b) *Definitions.* For purposes of this section:

(1) An employee has a *covered relationship* with:

(i) A person, other than a prospective employer described in § 2635.603(c), with whom the employee has or seeks a business, contractual, or other financial relationship that involves other than a routine consumer transaction;

Note 1 to paragraph (b)(1)(i): An employee who is seeking employment within the meaning of § 2635.603 must comply with subpart F of this part rather than with this section.

(ii) A person who is a member of the employee's household, or who is a relative with whom the employee has a close personal relationship;

(iii) A person for whom the employee's spouse, parent, or child is, to the employee's knowledge, serving or seeking to serve as an officer, director, trustee, general partner, agent, attorney, consultant, contractor, or employee;

(iv) Any person for whom the employee has, within the last year, served as officer, director, trustee, general partner, agent, attorney, consultant, contractor, or employee; or

(v) An organization, other than a political party described in 26 U.S.C. 527(e), in which the employee is an active participant. Participation is active if, for example, it involves service as an official of the organization or in a capacity similar to that of a committee or subcommittee chairperson or spokesperson, or participation in directing the activities of the organization. In other cases, significant time devoted to promoting specific programs of the organization, including coordination of fundraising efforts, is an indication of active participation. Payment of dues or the donation or solicitation of financial support does not, in itself, constitute active participation.

(2) *Direct and predictable effect* has the meaning set forth in § 2635.402(b)(1).

(3) *Particular matter involving specific parties* has the meaning set forth in § 2640.102(l) of this chapter.

Example 1 to paragraph (b): An employee of the General Services Administration (GSA) has made an offer to purchase a restaurant owned by a local developer. The developer has submitted an offer in response to a GSA solicitation for the lease of office space. Under the circumstances, the GSA employee would be correct in concluding that a reasonable person would be likely to question their impartiality if they were to participate in evaluating that developer's or its competitor's lease proposal.

Example 2 to paragraph (b): An employee of the Department of Labor is providing technical assistance in drafting occupational safety and health legislation that will affect all employers of five or more persons. The employee's spouse is employed as an administrative assistant by a large corporation that will incur additional costs if the proposed legislation is enacted. Because the legislation is not a particular matter involving specific parties, the employee may continue to work on the legislation and need not be concerned that the spouse's employment with an affected corporation would raise a question concerning the employee's impartiality.

Example 3 paragraph (b): An employee of the Bureau of Land Management (BLM) is studying environmental problems created by the use of hazardous substances on a particular section of public land. BLM has a contract with an environmental services company to produce a water quality study of the groundwater under this section of land along with a recommendation about how to remediate any problems that are found. The BLM employee will use the study to help determine the extent of the damage and to recommend a solution to any problems that are revealed. The employee's parent has accepted a job with this environmental services company and will be signing and submitting the report of the company's findings. Under these circumstances, the employee would be correct in concluding that a reasonable person would be likely to question their impartiality if they were to continue participating in the study related to this parcel of public land.

Example 4 to paragraph (b): An engineer has just resigned from a position as vice president of an electronics company in order to accept employment with the Federal Aviation Administration (FAA) in a position involving procurement responsibilities. Although the employee did not receive

a covered payment in connection with the resignation and has severed all financial ties with the firm, under the circumstances the employee would be correct in concluding that this former service as an officer of the company would be likely to cause a reasonable person to question their impartiality if they were to participate in the administration of an FAA contract for which the firm is a first-tier subcontractor.

Example 5 to paragraph (b): An employee of the Internal Revenue Service (IRS) is a member of a private organization whose purpose is to restore a Victorian-era railroad station, and chairs its annual fundraising drive. Under the circumstances, the employee would be correct in concluding that this active membership in the organization would be likely to cause a reasonable person to question their impartiality if they were to participate in an IRS determination regarding the tax-exempt status of the organization.

Example 6 to paragraph (b): An employee of the Department of Defense (DoD) has responsibility for testing avionics produced by a large Air Force contractor. The employee just learned that their adult child accepted a staff position in the human resources division of that contractor. Although the DoD employee has a covered relationship with the contractor that employs their child, the employee could justifiably conclude that a reasonable person would not be likely to question their impartiality because the child's work is unrelated to the avionics contract.

Example 7 to paragraph (b): An employee of the Department of Defense (DoD) leads the office that is testing a new type of jet engine produced by a multinational conglomerate's aviation division. The employee's lifelong best friend is the head of the conglomerate's aviation division and is responsible for presenting and promoting the new jet engine. Although the DoD employee does not have a covered relationship under paragraph (b)(1) of this section, the employee is concerned that, under paragraph (a)(3) of this section, questions regarding their impartiality could be raised. Here, the employee could justifiably conclude that a reasonable person would be likely to question their impartiality if they were to continue performing duties related to this jet engine.

(c) *Determination by agency designee.* (1) When the agency designee has information concerning a potential appearance problem arising from either the financial interest of a member of the employee's household in a particular matter involving specific parties or a particular matter involving specific parties in which a person with whom the employee has a covered relationship is a party or represents a party, the agency designee may make an independent determination as to whether a reasonable person with knowledge of the relevant facts would be likely to question the employee's impartiality in the matter. Ordinarily, the agency designee's determination will be initiated by information provided by the employee pursuant to paragraph (a) of this section. However, at any time, including after an employee has recused from participating in a particular matter pursuant to paragraph (e) of this section, agency designees may make this determination on their own initiative or when requested by the employee's supervisor or any other person responsible for the employee's assignment.

(2) If the agency designee determines that the employee's impartiality is likely to be questioned, the agency designee must then determine, in accordance with paragraph (d) of this section, whether the employee should be authorized to participate in the matter. If the agency designee determines that the employee's participation should not be authorized, the employee must recuse from participating in the particular matter in accordance with paragraph (e) of this section.

(3) If the agency designee determines that the employee's impartiality is not likely to be questioned, the agency designee may advise the employee, including an employee who has reached a contrary conclusion under paragraph (a) of this section, that the employee's participation in the matter would be proper.

(d) *Authorization by agency designee.* When an employee's participation in a particular matter involving specific parties would not violate 18 U.S.C. 208(a), but would raise a question in the mind of a reasonable person about the employee's impartiality, the agency designee may authorize the employee to participate in the matter based on a determination, made in light of all relevant circumstances, that the interest of the Government in the employee's participation outweighs the concern that a reasonable person may question the integrity of the agency's programs and operations.

(1) Factors which may be taken into consideration include:

(i) The nature of the relationship involved;

(ii) The effect that resolution of the matter would have upon the financial interests of the person involved in the relationship;

(iii) The nature and importance of the employee's role in the matter, including the extent to which the employee is called upon to exercise discretion in the matter;

(iv) The sensitivity of the matter;

(v) The difficulty of reassigning the matter to another employee; and

(vi) Adjustments that may be made in the employee's duties that would reduce or eliminate the likelihood that a reasonable person would question the employee's impartiality.

(2) Authorization by the agency designee will be documented in writing at the agency designee's discretion or when requested by the employee. An employee who has been authorized to participate in a particular matter involving specific parties may not thereafter recuse from participating in the matter on the basis of an appearance problem involving the same circumstances that have been considered by the agency designee.

Example 1 to paragraph (d): The Deputy Director of Personnel for the Department of the Treasury and an attorney with the Department's Office of General Counsel are general partners in a real estate partnership. The Deputy Director advises their supervisor, the Director of Personnel, of the relationship upon being assigned to a selection panel for a position for which the partner has applied. If selected, the partner would receive a substantial increase in salary. The agency designee cannot authorize the Deputy Director to participate on the panel under the authority of this section because the Deputy Director is prohibited by criminal statute, 18 U.S.C. 208(a), from participating in a particular matter affecting the financial interest of a person who is their general partner. See § 2635.402.

Example 2 paragraph (d): A new employee of the Securities and Exchange Commission is assigned to an investigation of insider trading by the brokerage house where they have recently been employed. Because of the sensitivity of the investigation, the agency designee may be unable to conclude that the Government's interest in the employee's participation in the investigation outweighs the concern that a reasonable person may question the integrity of the investigation, even though the employee has severed all financial ties with the company. Based on consideration of all relevant circumstances, the agency designee might determine, however, that it is in the interest of the Government for the employee to participate in the review of

a routine filing by the particular brokerage house.

Example 3 paragraph (d): An Internal Revenue Service employee involved in a long and complex tax audit learns that their child has just accepted an entry-level management position with a corporation whose taxes are the subject of the audit. Because the audit is essentially complete and because the employee is the only one with an intimate knowledge of the case, the agency designee might determine, after considering all relevant circumstances, that it is in the Government's interest for the employee to complete the audit, which is subject to additional levels of review.

(e) *Recusal.* Unless the employee is authorized to participate in the matter under paragraph (d) of this section, an employee may not participate in a particular matter involving specific parties when the employee or the agency designee has concluded, in accordance with paragraph (a) or (c) of this section, that the financial interest of a member of the employee's household, or the role of a person with whom the employee has a covered relationship, is likely to raise a question in the mind of a reasonable person about the employee's impartiality. Recusal is accomplished by not participating in the matter. When the covered relationship is with a former employer, this recusal requirement is for a period of one year after the date of the employee's resignation from the position with the former employer.

(1) *Notification.* Employees who become aware of the need to recuse from participating in a particular matter involving specific parties to which they have been assigned must take whatever steps are necessary to ensure that they do not participate in the matter. Appropriate oral or written notification of their recusal may be made to an agency ethics official, coworkers, or a supervisor to document and help effectuate the recusal.

(2) *Documentation.* Employees need not file written recusal statements unless they are required by part 2634 of this chapter to file written evidence of compliance with an ethics agreement with the Office of Government Ethics or a designated agency ethics official, or are specifically directed by an agency ethics official or the person responsible for their assignments to file written recusal statements. However, it is often prudent for employees to create a record of their actions by providing written notice to an agency ethics official, a supervisor, or other appropriate official.

(f) *Irrelevant considerations.* An employee's reputation for honesty and integrity is not a relevant consideration for purposes of any determination required by this section.

Note 2 to § 2635.502: Nothing in this section should be construed to suggest that employees should not participate in a matter because of their political, religious, or moral views.

§ 2635.503 Covered payments from former employers.

(a) *Recusal requirement.* Except as provided in paragraph (c) of this section, an employee must recuse for two years from participating in any particular matter involving specific parties in which the employee's former employer is a party or represents a party if the employee received a covered payment from that person. The two-year period of recusal begins to run on the date that the covered payment is received.

Example 1 to paragraph (a): Following confirmation hearings and one month before their scheduled swearing in, a nominee to the position of Assistant Secretary of a department received a covered payment from their employer. For one year and 11 months after their swearing in, the Assistant Secretary may not participate in any particular matter to which the former employer is a party.

Example 2 paragraph (a): An employee received a covered payment from their former employer, a coal mine operator, prior to entering on duty with the Department of the Interior. For two years thereafter, the employee may not participate in a determination regarding the former employer's obligation to reclaim a particular mining site, because the former employer is a party to the matter. However, the employee may help to draft reclamation legislation affecting all coal mining operations because this legislation does not involve any parties.

Example 3 to paragraph (a): An architect accepts a position with the Army Corps of Engineers and resigns from a private architecture partnership. One month after beginning this new position, the architect receives a covered payment from the partnership. The architect may not participate in any particular matter involving specific parties in which the former partnership is a party until two years after receipt of the covered payment, which will be 25 months after beginning service with the Corps. Because the payment was not received before the architect became an executive branch employee, agency ethics officials must also review the payment to determine whether it constituted a supplementation of salary under 18 U.S.C. 209.

(b) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Covered payment* means any item, including cash or an investment interest, with a value in excess of $10,000, which is paid:

(i) On the basis of a determination made after it became known to the former employer that the individual was being considered for or had accepted a Government position; and

(ii) Other than pursuant to a qualifying program.

(2)(i) A *qualifying program* is:

(A) A compensation, partnership, or benefits program that is contained in bylaws, a contract, or other written form, and does not treat individuals entering Government service more favorably than other individuals; or

(B) A program that is not contained in written form, but is demonstrated by a history of similar payments made to others not entering Government service.

(ii) When a program is established in written form, any history of making similar payments to others not entering Government service that is contrary to an express provision of the written plan is not relevant to the evaluation of whether it is a qualifying program.

Example 1 to paragraph (b)(2): The vice president of a small corporation is nominated to be an ambassador. In recognition of service to the corporation, the board of directors votes to pay the departing vice president $50,000 upon confirmation in addition to the regular severance payment provided for by the corporate bylaws. The regular severance payment is not a covered payment because it was made pursuant to a qualifying program. The gratuitous payment of $50,000 is a covered payment, because the corporation had not made similar payments to other departing officers.

(3) *Former employer* includes any person which the employee served as an officer, director, trustee, general partner, agent, attorney, consultant, contractor, or employee. Payments from an officer, employee, or agent of a former employer will be considered to be payments from the former employer.

Note 1 to paragraph (b)(3): The definition of *former employer* includes former clients for whom an employee may have served as an agent, attorney, consultant, or contractor.

(c) *Waiver of recusal.* The recusal requirement of this section may be waived based on a finding that the amount of the payment was not so substantial as to cause a reasonable person to question the employee's ability to act impartially in a matter in which the former employer is or represents a party. The waiver must be

in writing and may be given only by the head of the agency or, when the recipient of the payment is the head of the agency, by the President or the President's designee. Waiver authority may be delegated by the head of an agency to any person who has been delegated authority to issue individual waivers under 18 U.S.C. 208(b) for the employee who is the recipient of the covered payment.

Subpart F—Seeking Other Employment

§ 2635.601 Overview.

This subpart contains a recusal requirement that applies to employees when seeking non-Federal employment with persons whose financial interests would be directly and predictably affected by particular matters in which the employees participate personally and substantially. Specifically, it addresses the requirement of 18 U.S.C. 208(a) that an employee not participate personally and substantially in any particular matter that, to the employee's knowledge, will have a direct and predictable effect on the financial interests of a person with whom the employee is negotiating or has any arrangement concerning prospective employment. See § 2635.402 and § 2640.103 of this chapter. Beyond the statutory requirement in 18 U.S.C. 208(a), this subpart also addresses issues of lack of impartiality that require recusal from particular matters affecting the financial interests of a prospective employer when an employee's actions in seeking employment fall short of actual employment negotiations. In addition, this subpart contains the statutory notification requirements that apply to public filers when they negotiate for or have agreements of future employment or compensation. Specifically, it addresses the requirements of section 17 of the Representative Louise McIntosh Slaughter Stop Trading on Congressional Knowledge Act (STOCK Act), Public Law 112–105, 126 Stat. 303, that a public filer must submit a written statement identifying the entity involved in the negotiations or agreement within three business days after commencement of such negotiations or agreement and must submit a notification of recusal whenever there is a conflict of interest or an appearance of a conflict of interest.

§ 2635.602 Applicability and related considerations.

(a) *Applicability.* (1) To ensure that an employee does not violate 18 U.S.C. 208(a), section 17 of the STOCK Act, or the principles of ethical conduct contained in § 2635.101(b), an employee who is seeking employment or who has an arrangement concerning prospective employment must comply with the applicable recusal requirements of §§ 2635.604 and 2635.606 if particular matters in which the employee will be participating personally and substantially would, to the employee's knowledge, directly and predictably affect the financial interests of a prospective employer or of a person with whom the employee has an arrangement concerning prospective employment. Compliance with this subpart also will ensure that the employee does not violate subpart D or E of this part. In addition, a public filer who negotiates for or has an agreement of future employment or compensation must comply with the requirements of § 2635.607.

(2) An employee who is seeking employment with a person whose financial interests are not, to the employee's knowledge, affected directly and predictably by particular matters in which the employee participates personally and substantially has no obligation to recuse under this subpart. In addition, nothing in this subpart requires an employee, other than a public filer, to notify anyone that the employee is seeking employment unless a notification is necessary to implement a recusal pursuant to § 2635.604(b). A public filer who negotiates for or has an agreement of future employment or compensation must comply with the notification requirements in § 2635.607. An employee may, however, be subject to other statutes that impose requirements on employment contacts or discussions, such as 41 U.S.C. 2103, which is applicable to agency officials involved in certain procurement matters. Employees are encouraged to consult with their ethics officials if they have any questions about how this subpart may apply to them. Ethics officials are not obligated by this subpart to inform supervisors that employees are seeking employment.

Example 1 to paragraph (a): Recently, an employee of the Department of Education submitted a resume to the University of Delaware for a job opening. The employee has begun seeking employment. However, because the employee is not participating in any particular matters affecting the University of Delaware, there is no requirement that anyone be notified that the employee has begun seeking employment.

Example 2 to paragraph (a): The employee in example 1 to this paragraph (a) has been approached about an employment opportunity at the University of Maryland. Because the University of Maryland has applied for grants on which the employee has been assigned to work in the past, the employee wants to make certain that they do not violate the ethics rules. The employee contacts an ethics official to discuss the matter. The employee informs the ethics official that they are not currently participating in any particular matters affecting the University of Maryland. As a result, the ethics official advises the employee that they will have no notification obligations under this subpart. However, the ethics official cautions the employee that, if the employee is assigned to participate in a particular matter affecting the University of Maryland while they are seeking employment with the University, they must take whatever steps are necessary to avoid working on the grant, in accordance with § 2635.604.

(b) *Related restrictions*—(1) *Outside employment while a Federal employee.* An employee who is contemplating outside employment to be undertaken concurrently with the employee's Federal employment must abide by any limitations applicable to the employee's outside activities under subparts G and H of this part, including any requirements under supplemental agency regulations to obtain prior approval before engaging in outside employment or activities and any prohibitions under supplemental agency regulations related to outside employment or activities. The employee must also comply with any applicable recusal requirement of this subpart, as well as any applicable recusal requirements under subpart D or E of this part as a result of the employee's outside employment activities.

(2) *Post-employment restrictions.* An employee who is contemplating employment to be undertaken following the termination of the employee's Federal employment should consult an agency ethics official to obtain advice regarding any post-employment restrictions that may be applicable. The regulation implementing the Governmentwide post-employment statute, 18 U.S.C. 207, is contained in part 2641 of this chapter. Employees are cautioned that they may be subject to additional statutory prohibitions on post-employment acceptance of compensation from contractors, such as 41 U.S.C. 2104.

(3) *Interview trips and entertainment.* When a prospective employer who is a prohibited source as defined in § 2635.203(d) offers to reimburse an

employee's travel expenses, or provide other reasonable amenities incident to employment discussions, the employee may accept such amenities in accordance with § 2635.204(e)(3). When a prospective employer is a foreign government or international organization, the employee must also comply with the Foreign Gifts and Decorations Act, 5 U.S.C. 7342.

§ 2635.603 Definitions.

For purposes of this subpart:

(a) *Employment* means any form of non-Federal employment or business relationship involving the provision of personal services by the employee, whether to be undertaken at the same time as or subsequent to Federal employment. It includes but is not limited to personal services as an officer, director, employee, agent, attorney, consultant, contractor, general partner, or trustee.

Example 1 to paragraph (a): An employee of the Bureau of Indian Affairs who has announced their intention to retire is approached by Tribal representatives concerning a possible consulting contract with the tribe. The contractual relationship the tribe wishes to negotiate is employment for purposes of this subpart.

Example 2 to paragraph (a): An employee of the Department of Health and Human Services is invited to a meeting with officials of a nonprofit corporation to discuss the possibility of serving as a member of the corporation's board of directors. Service, with or without compensation, as a member of the board of directors constitutes employment for purposes of this subpart.

Example 3 to paragraph (a): An employee at the Department of Energy volunteers without compensation to serve dinners at a homeless shelter each month. The employee's uncompensated volunteer services in this case are not considered an employment or business relationship for purposes of this subpart.

(b) An employee is *seeking employment* once the employee has begun seeking employment within the meaning of paragraph (b)(1) of this section and until the employee is no longer seeking employment within the meaning of paragraph (b)(2) of this section.

(1) An employee has begun seeking employment if the employee has directly or indirectly:

(i) Engaged in negotiations for employment with any person. For purposes of this paragraph (b)(1)(i), as for 18 U.S.C. 208(a) and section 17 of the STOCK Act, the term *negotiations* means discussion or communication with another person, or such person's agent or intermediary, mutually conducted with a view toward reaching an agreement regarding possible employment with that person. The term is not limited to discussions of specific terms and conditions of employment in a specific position;

(ii) Made an unsolicited communication to any person, or such person's agent or intermediary, regarding possible employment with that person. However, the employee has not begun seeking employment if that communication was for the sole purpose of requesting a job application; or

(iii) Made a response, other than rejection, to an unsolicited communication from any person, or such person's agent or intermediary, regarding possible employment with that person.

(2) An employee is no longer seeking employment when:

(i) The employee or the prospective employer rejects the possibility of employment and all discussions of possible employment have terminated; or

(ii) Two months have transpired after the employee's dispatch of an unsolicited resume or employment proposal, provided the employee has received no indication of interest in employment discussions from the prospective employer.

(3) For purposes of this paragraph (b), a response that defers discussions until the foreseeable future does not constitute rejection of an unsolicited employment overture, proposal, or resume nor rejection of a prospective employment possibility.

Example 1 to paragraph (b): A paralegal at the Department of the Army is in the third year of law school. The paralegal's neighbor, a partner in a large law firm in the community, invited the paralegal to the law firm for a visit. The paralegal accepted the offer and met with an associate at the firm. The associate shared with the paralegal their experiences looking for a legal position, discussed what they do in their position at the law firm, and explained why they chose that law firm. There was no discussion of possible employment with the firm. The Army paralegal is not seeking employment at this time. The purpose of the visit was informational only.

Example 2 to paragraph (b): An employee of the Defense Contract Audit Agency (DCAA) is auditing the overhead accounts of an Army contractor. While at the contractor's headquarters, the head of the contractor's accounting division tells the employee that the division is thinking about hiring another accountant and asks whether the employee might be interested in leaving DCAA. The DCAA employee asks what kind of work would be involved. The DCAA employee has begun seeking employment because they made a response other than a rejection to the communication regarding possible employment with the Army contractor, although they have not yet begun negotiating for employment.

Example 3 to paragraph (b): The DCAA employee and the head of the contractor's accounting division in example 2 to this paragraph (b) have a meeting to discuss the duties of the position that the accounting division would like to fill and the DCAA employee's qualifications for the position. They also discuss ways the DCAA employee could remedy one of the missing qualifications, and the employee indicates a willingness to obtain the proper qualifications. They do not discuss salary. The employee has engaged in negotiations regarding possible employment with the contractor.

Example 4 to paragraph (b): An employee at the Department of Energy (DOE) lists their job duties and employment experience in a profile on an online, business-oriented social networking service. The employee's profile is not targeted at a specific prospective employer. The employee has not begun seeking employment because the posting of a profile or resume is not an unsolicited communication with any prospective employer.

Example 5 to paragraph (b): The DOE employee in example 4 to this paragraph (b) was recently notified that a representative of a university has viewed their profile. The employee still has not begun seeking employment with the university. Subsequently, a representative of the university contacts the employee through the online forum to inquire whether the employee would be interested in working for the university, to which the employee makes a response other than rejection. At this point, the employee has begun seeking employment with the university until they reject the possibility of employment and all discussions of possible employment have terminated.

Example 6 to paragraph (b): The DOE employee in examples 4 and 5 to this paragraph (b) receives emails from various companies in response to the online profile. The employee does not respond. The employee has not begun seeking employment with the

companies because they have not made a response.

Example 7 to paragraph (b): An official of a State Health Department compliments the work of an employee of the Centers for Medicare & Medicaid Services (CMS), and asks the CMS employee to reach out if they are ever interested in leaving Federal service. The employee explains to the State official that they are very happy with their job at CMS and is not interested in another job. The employee thanks the official for the professional compliment, and adds that they'll remember the official's interest if they ever decide to leave the Government. The employee has rejected the unsolicited employment overture and has not begun seeking employment.

Example 8 to paragraph (b): The employee in the example 7 to this paragraph (b) responds by stating that they cannot discuss future employment while they are working on a project affecting the State's health care funding but would like to discuss employment with the State when the project is completed. Because the employee has merely deferred employment discussions until the foreseeable future, they have begun seeking employment with the State Health Department.

Example 9 to paragraph (b): Three months prior to the end of the current administration, a political appointee at a large department receives a telephone call from the managing partner of an international law firm. The managing partner asks if the official would be interested in joining the law firm. The official says, ''I am not talking to anyone about employment until I leave the Government.'' The official has rejected the unsolicited employment overture and has not begun seeking employment.

Example 10 to paragraph (b): A geologist employed by the U.S. Geological Survey sends a resume to an oil company. The geologist has begun seeking employment with that oil company and will be seeking employment for two months from the date the resume was mailed, provided the geologist does not receive a response indicating an interest in employment discussions. A letter merely acknowledging receipt of the resume is not an indication of interest in employment discussions. However, if the geologist withdraws the application or is notified within the two-month period that the resume has been rejected, they will no longer be seeking employment with the oil company as of the date they make such withdrawal or receive such notification.

(c) *Prospective employer* means any person with whom the employee is seeking employment. When contacts that constitute seeking employment are made by or with an agent or other intermediary, the term prospective employer means:

(1) A person who uses that agent or other intermediary for the purpose of seeking to establish an employment relationship with the employee if the agent identifies the prospective employer to the employee; and

(2) A person contacted by the employee's agent or other intermediary for the purpose of seeking to establish an employment relationship if the agent identifies the prospective employer to the employee.

Example 1 to paragraph (c): An employee of the Federal Aviation Administration (FAA) has retained an employment search firm to help them find another job. The search firm has just reported to the FAA employee that it has given their resume to and had promising discussions with two airport authorities, which the search firm identifies to the employee. Even though the employee has not personally had employment discussions with either airport authority, each airport authority is their prospective employer. The employee began seeking employment with each airport authority upon learning its identity and that it has been given their resume.

Example 2 to paragraph (c): An employee pays for an online resume distribution service, which sends their resume to recruiters that specialize in their field. The online service has just notified the employee that it sent their resume to Software Company A and Software Company B. Even though the employee has not personally had employment discussions with either company, each software company is their prospective employer. The employee began seeking employment with each company upon learning from the online service that Software Company A and Software Company B had been given their resume by the intermediary.

(d) *Direct and predictable effect, particular matter,* and *personal and substantial* have the respective meanings set forth in § 2635.402(b)(1), (3), and (4).

(e) *Public filer* means a person required to file a public financial disclosure report as set forth in § 2634.202 of this chapter.

§ 2635.604 Recusal while seeking employment.

(a) *Obligation to recuse.* (1) Except as provided in paragraph (a)(2) of this section or when the employee's participation has been authorized in accordance with § 2635.605, the employee may not participate personally and substantially in a particular matter that, to the employee's knowledge, has a direct and predictable effect on the financial interests of a prospective employer with whom the employee is seeking employment within the meaning of § 2635.603(b). Recusal is accomplished by not participating in the particular matter.

(2) The employee may participate in a particular matter under paragraph (a)(1) of this section when:

(i) The employee's only communication with the prospective employer in connection with the search for employment is the submission of an unsolicited resume or other employment proposal;

(ii) The prospective employer has not responded to the employee's unsolicited communication with a response indicating an interest in employment discussions; and

(iii) The matter is not a particular matter involving specific parties.

Example 1 to paragraph (a): A scientist is employed by the National Science Foundation (NSF) as a special Government employee to serve on a panel that reviews grant applications to fund research relating to deterioration of the ozone layer. The scientist is discussing possible employment with a university that received an NSF grant several years ago to study the effect of fluorocarbons but has no current grant applications pending before NSF. The employee is seeking employment, but does not need to recuse because there is no particular matter that would have a direct and predictable effect on the financial interests of the prospective employer. Recusal would be required if the university submits a new application for the panel's review.

Example 2 to paragraph (a): An employee of the Food and Drug Administration is developing a regulation on research criteria for approving prescription drugs. They begin discussing possible employment with a pharmaceutical company. The employee may not participate personally and substantially in the development of the regulation because they have begun employment discussions with the pharmaceutical company and the regulation is a particular matter of general applicability which would have a direct and predictable effect on the financial interests of the pharmaceutical company.

Example 3 to paragraph (a): A special Government employee of the Federal Deposit Insurance Corporation (FDIC) is assigned to advise the FDIC on rules

applicable to all member banks. The employee mails an unsolicited letter to a member bank offering services as a contract consultant. Although the employee is seeking employment, the employee may participate in this particular matter of general applicability until receipt of some response indicating an interest in discussing the employment proposal. A letter merely acknowledging receipt of the proposal is not an indication of interest in employment discussions.

Example 4 to paragraph (a): An employee of the Occupational Safety and Health Administration is conducting an inspection of one of several textile companies to which they sent an unsolicited resume. The employee may not participate personally and substantially in the inspection because they are seeking employment and the inspection is a particular matter involving specific parties that will affect the textile company.

(b) *Notification.* Employees who become aware of the need to recuse from participating in a particular matter to which they have been assigned must take whatever steps are necessary to ensure that they do not participate in the matter. Appropriate oral or written notification of their recusal may be made to an agency ethics official, coworkers, or a supervisor to document and help effectuate the recusal. Public filers must comply with additional notification requirements set forth in § 2635.607.

Example 1 to paragraph (b): An employee of the Department of Veterans Affairs (VA) is participating in the audit of a contract for laboratory support services. Before sending a resume to a lab which is a subcontractor under the VA contract, the employee should recuse from participating in the audit. Because the employee cannot withdraw from participating in the contract audit without supervisor approval, the employee should notify the supervisor of the need to recuse for ethics reasons so that appropriate adjustments in work assignments can be made.

Example 2 to paragraph (b): An employee of the Food and Drug Administration (FDA) is contacted in writing by a pharmaceutical company concerning possible employment with the company. The employee is reviewing an application from the same pharmaceutical company, which is seeking FDA approval for a new drug product. Once the employee makes a response that is not a rejection to the company's communication concerning possible employment, the employee must recuse from further participation in the review of the application. When the employee has authority to ask a colleague to assume reviewing responsibilities, they may accomplish recusal by transferring the work to the colleague. However, to ensure that the colleague and others with whom they had been working on the review do not seek their advice regarding the review of the application or otherwise involve them in the matter, it may be necessary for the employee to advise those individuals of the recusal.

(c) *Documentation.* Employees, other than public filers, need not file written recusal statements unless they are required by part 2634 of this chapter to file written evidence of compliance with an ethics agreement with the Office of Government Ethics or a designated agency ethics official, or are specifically directed by an agency ethics official or the person responsible for their assignments to file written recusal statements. However, it is often prudent for employees to create a record of their actions by providing written notice to an agency ethics official, a supervisor, or other appropriate official. Public filers must comply with the documentation requirements set forth in § 2635.607.

Example 1 to paragraph (c): The General Counsel of a regulatory agency will be engaging in discussions regarding possible employment as corporate counsel of a regulated entity. Matters directly affecting the financial interests of the regulated entity are pending within the Office of General Counsel, but the General Counsel will not be called upon to act in any such matter because signature authority for that particular class of matters has been delegated to an Assistant General Counsel. Because the General Counsel is responsible for assigning work within the Office of General Counsel, they can, in fact, accomplish recusal by simply avoiding any involvement in matters affecting the regulated entity. However, because it is likely to be assumed by others that the General Counsel is involved in all matters within the cognizance of the Office of General Counsel, they would benefit from filing a written recusal statement with an agency ethics official or the Commissioners of the regulatory agency and providing their subordinates with written notification of the recusal. The General Counsel may also be specifically directed by an agency ethics official or the Commissioners to file a written recusal statement. If the General Counsel is a public filer, they must comply with the documentation requirements set forth in § 2635.607.

(d) *Agency determination of substantial conflict.* When the agency determines that the employee's action in seeking employment with a particular person will require the employee to recuse from matters so central or critical to the performance of the employee's official duties that the employee's ability to perform the duties of the employee's position would be materially impaired, the agency may allow the employee to take annual leave or leave without pay while seeking employment, or may take other appropriate action.

§ 2635.605 Waiver or authorization permitting participation while seeking employment.

(a) *Waiver.* When, as defined in § 2635.603(b)(1)(i), an employee is engaged in employment negotiations for purposes of 18 U.S.C. 208(a), the employee may not participate personally and substantially in a particular matter that, to the employee's knowledge, has a direct and predictable effect on the financial interests of a prospective employer. The employee may participate in such matters only when the employee has received a written waiver issued under the authority of 18 U.S.C. 208(b)(1) or (3). These waivers are described in § 2635.402(d) and part 2640, subpart C, of this chapter. For certain employees, a regulatory exemption under the authority of 18 U.S.C. 208(b)(2) may also apply (see part 2640, subpart B, of this chapter, including § 2640.203(g) and (i)).

Example 1 to paragraph (a): An employee of the Department of Agriculture is negotiating for employment within the meaning of 18 U.S.C. 208(a) and § 2635.603(b)(1)(i) with an orange grower. In the absence of a written waiver issued under 18 U.S.C. 208(b)(1), the employee may not take official action on a complaint filed by a competitor alleging that the grower has shipped oranges in violation of applicable quotas.

(b) *Authorization by agency designee.* When an employee is seeking employment within the meaning of § 2635.603(b)(1)(ii) or (iii) and is not negotiating for employment, a reasonable person would be likely to question the employee's impartiality if the employee were to participate personally and substantially in a particular matter that, to the employee's knowledge, has a direct and predictable effect on the financial interests of any such prospective employer. The employee may participate in such matters only when the agency designee has authorized in writing the employee's participation in accordance

with the standards set forth in § 2635.502(d).

Example 1 to paragraph (b): Within the past month, an employee of the Department of Education mailed a resume to a university. The employee is thus seeking employment with the university within the meaning of § 2635.603(b)(1)(ii). In the absence of specific authorization by the agency designee in accordance with § 2635.502(d), the employee may not participate personally and substantially in an assignment to review a grant application submitted by the university.

§ 2635.606 Recusal based on an arrangement concerning prospective employment or otherwise after negotiations.

(a) *Employment or arrangement concerning employment.* An employee may not participate personally and substantially in a particular matter that, to the employee's knowledge, has a direct and predictable effect on the financial interests of the person by whom the employee is employed or with whom the employee has an arrangement concerning future employment, unless authorized to participate in the matter by a written waiver issued under the authority of 18 U.S.C. 208(b)(1) or (3), or by a regulatory exemption under the authority of 18 U.S.C. 208(b)(2). These waivers and exemptions are described in § 2635.402(d) and part 2640, subparts B and C, of this chapter.

Example 1 to paragraph (a): A military officer has accepted a job with a defense contractor that will begin six months after retirement from military service. During the remainder of Government employment, the officer may not participate personally and substantially in the administration of a contract with that particular defense contractor unless a written waiver is issued under the authority of 18 U.S.C. 208(b)(1).

Example 2 to paragraph (a): An accountant has just been offered a job with the Office of the Comptroller of the Currency (OCC) which involves a two-year limited appointment. The accountant's private employer, a large corporation, believes the job will enhance their skills and has agreed to give them a two-year unpaid leave of absence at the end of which they have agreed to return to work for the corporation. During the two-year period that the accountant is to be an OCC employee, they will have an arrangement concerning future employment with the corporation that will require recusal from participating personally and substantially in any particular matter that, to their knowledge, will have a direct and predictable effect on the corporation's financial interests.

(b) *Offer rejected or not made.* The agency designee for the purpose of § 2635.502(c) may, in an appropriate case, determine that an employee not covered by paragraph (a) of this section who has sought but is no longer seeking employment nevertheless will be subject to a period of recusal upon the conclusion of employment negotiations. Any such determination will be based on a consideration of all the relevant factors, including those listed in § 2635.502(d), and a determination that the concern that a reasonable person may question the integrity of the agency's decision-making process outweighs the Government's interest in the employee's participation in the particular matter.

Example 1 to paragraph (b): An employee of the Securities and Exchange Commission was relieved of responsibility for an investigation of a broker-dealer while seeking employment with the law firm representing the broker-dealer in that matter. The firm did not offer the partnership position the employee sought. Even though the employee is no longer seeking employment with the firm, they may continue to be recused from participating in the investigation based on a determination by the agency designee that the concern that a reasonable person might question whether, in view of the history of the employment negotiations, they could act impartially in the matter outweighs the Government's interest in their participation.

§ 2635.607 Notification requirements for public financial disclosure report filers regarding negotiations for or agreement of future employment or compensation.

(a) *Notification regarding negotiations for or agreement of future employment or compensation.* A public filer who is negotiating for or has an agreement of future employment or compensation with a non-Federal entity must file a statement notifying an agency ethics official of such negotiation or agreement within three business days after commencement of the negotiation or agreement. This notification statement must be in writing, must be signed by the public filer, and must include the name of the non-Federal entity involved in such negotiation or agreement and the date on which the negotiation or agreement commenced. When a public filer has previously complied with the notification requirement in this section regarding the commencement of negotiations, the filer need not file a separate notification statement when an agreement of future employment or compensation is reached with the previously identified non-Federal entity. There is also no requirement to file another notification when negotiations have been unsuccessful. However, employees may want to do so to facilitate the resumption of their duties.

Example 1 to paragraph (a): An employee of the Merit Systems Protection Board who is a public filer was in private practice prior to Government service. The employee receives a telephone call from a partner in a law firm who inquires as to whether they would be interested in returning to private practice. During this initial telephone call with the law firm partner, the employee indicates that they are interested in resuming private practice. The partner and employee discuss generally the types of issues that would need to be agreed upon if the employee were to consider a possible offer to serve as ''of counsel'' with the firm, such as salary, benefits, and type of work the employee would perform. The employee has begun negotiating for future employment with the law firm. Within three business days after this initial telephone call, the employee must file written notification of the negotiations with the agency ethics official.

Example 2 to paragraph (a): The employee in the example 1 to this paragraph (a) also negotiates a possible contract with a publisher to begin writing a textbook after leaving Government service. Within three business days after commencing negotiations, the employee must file written notification with the agency ethics official documenting this engagement in negotiations for future compensation with the book publisher.

(b) *Notification of recusal.* A public filer who files a notification statement pursuant to paragraph (a) of this section must file with an agency ethics official a notification of recusal whenever there is a conflict of interest or appearance of a conflict of interest with the non-Federal entity identified in the notification statement. The notification statement and the recusal statement may be contained in a single document or in separate documents.

(c) *Advance filing of notification and recusal statements.* When a public filer is seeking employment within the meaning of § 2635.603(b)(1)(ii) or (iii) or is considering seeking employment, the public filer may elect to file the notification statement pursuant to paragraph (a) of this section before negotiations have commenced and

before an agreement of future employment or compensation is reached. A public filer may also elect to file the recusal statement pursuant to paragraph (b) of this section before the public filer has a conflict of interest or appearance of a conflict of interest with the non-Federal entity identified in the notification statement. The public filer need not file the document again upon commencing negotiations or reaching an agreement of future employment or compensation. The advance filing of any such document is not construed as a statement that negotiations have or have not commenced or that a conflict of interest does or does not exist. Although the Office of Government Ethics encourages advance filing when a public filer anticipates a realistic possibility of negotiations or an agreement, the failure to make an advance filing does not violate this subpart or the principles of ethical conduct contained in § 2635.101(b).

Example 1 to paragraph (c): An employee of the Federal Labor Relations Authority who is a public filer began negotiating for future employment with a law firm. At the time the employee began negotiating for future employment with the law firm, they were not participating personally and substantially in a particular matter that, to their knowledge, had a direct and predictable effect on the financial interest of the law firm. Although the employee was not required to file a recusal statement because they did not have a conflict of interest or appearance of a conflict of interest with the law firm identified in the notification statement, the Office of Government Ethics encourages the employee to submit a notification of recusal at the same time that they file the notification statement regarding the negotiations for future employment in order to ensure that the requirement of paragraph (b) of this section is satisfied if a conflict of interest or an appearance of a conflict of interest later arises. The agency ethics official should counsel the employee on applicable requirements but is under no obligation to notify the employee's supervisor that the employee is negotiating for employment.

Example 2 to paragraph (c): An employee of the General Services Administration is contacted by a prospective employer regarding scheduling an interview for the following week to begin discussing the possibility of future employment. The employee discusses the matter with the ethics official and chooses to file a notification and recusal statement prior to the interview. The notification and recusal statement contain the identity of the prospective employer and an estimated date of when the interview will occur. The employee has complied with the notification requirement of section 17 of the STOCK Act.

(d) *Definition of agreement of future employment or compensation. Agreement of future employment or compensation* for the purposes of this section means any arrangement concerning employment that will commence after the termination of Government service. The term also means any arrangement to compensate in exchange for services that will commence after the termination of Government service. The term includes, among other things, an arrangement to compensate for teaching, speaking, or writing that will commence after the termination of Government service.

Subpart G—Misuse of Position

§ 2635.701 Overview.

This subpart contains provisions relating to the proper use of official time and authority, and of information and resources to which employees have access because of their Federal employment. This subpart sets forth standards relating to:

(a) Use of public office for private gain;

(b) Use of nonpublic information;

(c) Use of Government property; and

(d) Use of official time.

§ 2635.702 Use of public office for private gain.

An employee may not use their public office for their own private gain; for the endorsement of any product, service, or enterprise (except as otherwise permitted by this part or other applicable law or regulation); or for the private gain of friends, relatives, or persons with whom the employee is affiliated in a nongovernmental capacity, including nonprofit organizations of which the employee is an officer or member, and persons with whom the employee has or seeks employment or business relations. The specific prohibitions set forth in paragraphs (a) through (d) of this section apply this general standard, but are not intended to be exclusive or to limit the application of this section.

(a) *Inducement or coercion of benefits.* Employees may not use or permit the use of their Government position or title, or any authority associated with their public office, in a manner that is intended to coerce or induce another person, including a subordinate, to provide any benefit, financial or otherwise, to the employee or to friends, relatives, or persons with whom the employee is affiliated in a nongovernmental capacity.

Example 1 to paragraph (a): Offering to pursue a relative's consumer complaint over a household appliance, an employee of the Securities and Exchange Commission called the general counsel of the manufacturer and, in the course of discussing the problem, stated that they worked at the SEC and were responsible for reviewing the company's filings. The employee violated the prohibition against use of public office for private gain by invoking their official authority in an attempt to influence action to benefit the relative.

Example 2 to paragraph (a): An employee of the Department of Commerce was asked by a friend to determine why another office within the Department of Commerce had not yet granted an export license to the friend's firm. At a department-level staff meeting, the employee raised as a matter for official inquiry the delay in approval of the particular license and asked that the particular license be expedited. The official used their public office in an attempt to benefit the friend and, in acting as the friend's agent for the purpose of pursuing the export license with the Department of Commerce, may also have violated 18 U.S.C. 205.

(b) *Appearance of governmental sanction.* Except as otherwise provided in this part, employees may not use or permit the use of their Government position or title, or any authority associated with their public office, in a manner that could reasonably be construed to imply that their agency or the Government sanctions or endorses their personal activities or those of another. When teaching, speaking, or writing in a personal capacity, employees may refer to their official title or position only as permitted by § 2635.807(b). When providing a verbal or written recommendation, employees may only use their official title in response to a request for a recommendation or character reference based upon personal knowledge of the ability or character of an individual with whom they have dealt in the course of Federal employment or whom they are recommending for Federal employment.

Example 1 to paragraph (b): An employee of the Department of the Treasury who is asked to provide a letter of recommendation for a former subordinate or for an individual who worked for their team under a Government contract may provide the recommendation using official stationery and may sign the letter using their official title. If, however, the

request is for the recommendation of a personal friend with whom they have not dealt in the Government, the employee should not use official stationery or sign the letter of recommendation using their official title, unless the recommendation is for Federal employment. In writing the letter of recommendation for the personal friend, it may be appropriate for the employee to make a reference to their official position in the body of the letter.

Example 2 to paragraph (b): An employee of the Environmental Protection Agency (EPA) has a personal social media account. Under ''occupation,'' the employee writes ''Analyst at the Environmental Protection Agency.'' On the same social media account, the EPA employee occasionally discusses topics related to the environment, such as recycling, biking to work, and organic gardening. Even though the employee is discussing matters related to the EPA's mission and lists their position in the area designated for occupation, these facts alone would not reasonably be construed as implying governmental sanction or endorsement. The same employee may not, for example, redesign the social media account so that it prominently features the official EPA seal and make statements that either assert or imply that their opinions on environmental topics are sanctioned or endorsed by the Government.

(c) *Endorsements.* Employees may not use or permit the use of their Government position or title or any authority associated with their public office to endorse any product, service, or enterprise except:

(1) In furtherance of statutory authority to promote products, services, or enterprises; or

(2) As a result of documentation of compliance with agency requirements or standards or as the result of recognition for achievement given under an agency program of recognition for accomplishment in support of the agency's mission.

Example 1 to paragraph (c): A Commissioner of the Consumer Product Safety Commission (CPSC) may not appear in a television commercial and endorse an electrical appliance produced by a former employer, stating that it has been found by the CPSC to be safe for residential use.

Example 2 to paragraph (c): A Foreign Commercial Service officer from the Department of Commerce is asked by a United States telecommunications company to meet with representatives of the government of Spain, which is in the process of procuring telecommunications services and equipment. The company is bidding against five European companies, and the statutory mission of the Department of Commerce includes assisting the export activities of U.S. companies. As part of official duty activities, the Foreign Commercial Service officer may meet with Spanish officials and explain the advantages of procurement from the United States company.

Example 3 to paragraph (c): The Administrator of the Environmental Protection Agency may sign a letter to an oil company indicating that its refining operations are in compliance with Federal air quality standards even though the Administrator knows that the company has routinely displayed letters of this type in television commercials portraying it as a ''trustee of the environment for future generations.''

Example 4 to paragraph (c): An Assistant Attorney General may not use their official title or refer to their Government position in a book jacket endorsement of a novel about organized crime written by an author whose work they admire. Nor may they do so in a book review published in a newspaper.

(d) *Performance of official duties affecting a private interest.* To ensure that the performance of their official duties does not give rise to an appearance of use of public office for private gain or of giving preferential treatment, employees whose duties would affect the financial interests of a friend, relative, or person with whom they are affiliated in a nongovernmental capacity must comply with any applicable requirements of § 2635.502.

(e) *Use of terms of address and ranks.* Nothing in this section prohibits an employee who is ordinarily addressed using a general term of address, such as ''The Honorable'' or ''Judge,'' or a rank, such as a military or ambassadorial rank, from using that term of address or rank in connection with a personal activity.

§ 2635.703 Use of nonpublic information.

(a) *Prohibition.* Employees may not engage in financial transactions using nonpublic information, nor allow the improper use of nonpublic information to further their own private interests or those of another, whether through advice or recommendation, or by knowing unauthorized disclosure.

(b) *Definition of nonpublic information.* For purposes of this section, *nonpublic information* is information that the employee gains by reason of Federal employment and that the employee knows or reasonably should know has not been made available to the general public. It includes information that the employee knows or reasonably should know:

(1) Is routinely exempt from disclosure under 5 U.S.C. 552 or otherwise protected from disclosure by statute, Executive order, or regulation;

(2) Is designated as confidential by an agency; or

(3) Has not actually been disseminated to the general public and is not authorized to be made available to the public on request.

Example 1 to paragraph (b): A Navy employee learns in the course of official duties that a small corporation will be awarded a Navy contract for electrical test equipment. The employee may not take any action to purchase stock in the corporation or its suppliers, and may not advise friends or relatives to do so until after public announcement of the award. Such actions could violate Federal securities statutes as well as this section.

Example 2 to paragraph (b): A General Services Administration employee involved in evaluating proposals for a construction contract cannot disclose the terms of a competing proposal to a friend employed by a company bidding on the work. Prior to award of the contract, bid or proposal information is nonpublic information specifically protected by 41 U.S.C. 2102.

Example 3 to paragraph (b): An employee is a member of a source selection team assigned to review the proposals submitted by several companies in response to an Army solicitation for spare parts. As a member of the evaluation team, the employee has access to proprietary information regarding the production methods of Alpha Corporation, one of the competitors. The employee may not use that information to assist Beta Company in drafting a proposal to compete for a Navy spare parts contract. The Federal Acquisition Regulation in 48 CFR parts 3, 14, and 15 restricts the release of information related to procurements and other contractor information that must be protected under 18 U.S.C. 1905 and 41 U.S.C. 2102.

Example 4 to paragraph (b): An employee of the Nuclear Regulatory Commission inadvertently includes a document that is exempt from disclosure with a group of documents released in response to a Freedom of Information Act request. Regardless of whether the document is used improperly, the employee's disclosure does not violate this section because it was not a knowing unauthorized disclosure made for the purpose of furthering a private interest.

Example 5 to paragraph (b): An employee of the Army Corps of Engineers is actively involved in the activities of an organization whose goals relate to protection of the environment. The employee may not, other than as permitted by agency procedures, give the organization or a newspaper reporter nonpublic information about long-range plans to build a particular dam.

§ 2635.704 Use of Government property.

(a) *Standard.* Employees have a duty to protect and conserve Government property and may not use such property, or allow its use, for other than authorized purposes.

(b) *Definitions.* For purposes of this section:

(1) *Government property* includes any form of real or personal property in which the Government has an ownership, leasehold, or other property interest as well as any right or other intangible interest that is purchased with Government funds, including the services of contractor personnel. The term includes but is not limited to office supplies, telephone and other telecommunications equipment and services, Government mail, computers and other electronic devices, printing and reproduction facilities, Government records, Government email and social media accounts, and Government vehicles.

(2) *Authorized purposes* are those purposes for which Government property is made available to members of the public or those purposes authorized in accordance with law or regulation. Authorized purposes include but are not limited to those uses of Government property that are in accordance with an agency's limited or *de minimis* personal use policy.

Example 1 to paragraph (b): As permitted under their agency's *de minimis* personal use policy, an employee may send an email from a Government email account to a former college roommate to schedule lunch for the following day.

Example 2 to paragraph (b): An employee of the Commodity Futures Trading Commission whose office computer provides access to a commercial service providing information for investors may not use that service for personal investment research.

Example 3 to paragraph (b): In accordance with Office of Personnel Management regulations at part 251 of this title, an attorney employed by the Department of Justice may be permitted to use their office computer and agency photocopy equipment to prepare a paper to be presented at a conference sponsored by a professional association of which they are a member.

§ 2635.705 Use of official time.

(a) *Use of an employee's own time.* Unless authorized in accordance with law or regulations to use such time for other purposes, employees must use official time in an honest effort to perform official duties. Employees not under a leave system, including Presidential appointees exempted under 5 U.S.C. 6301(2), have an obligation to expend an honest effort and a reasonable proportion of their time in the performance of official duties.

Example 1 to paragraph (a): A disability claims examiner of the Social Security Administration may use official time to engage in certain representational activities on behalf of the employee union of which they are a member. Under 5 U.S.C. 7131, this is a proper use of official time even though it does not involve performance of assigned duties as a disability claims examiner.

Example 2 to paragraph (a): A pharmacist employed by the Department of Veterans Affairs has been granted an excused absence to participate as a speaker in a conference on drug abuse sponsored by the professional association to which they belong. Even if an excused absence granted by an agency in accordance with Governmentwide personnel guidance would allow employees to be absent from their official duties without charge to their annual leave accounts, such absence would not be on official time.

(b) *Use of a subordinate's time.* Employees may not encourage, direct, coerce, or request a subordinate to use official time to perform activities other than those required in the performance of official duties or authorized in accordance with law or regulation.

Example 1 to paragraph (b): A supervisory employee of the Department of Housing and Urban Development may not ask an assistant to run personal errands for the employee during duty hours. Further, directing or coercing a subordinate to perform such activities during nonduty hours constitutes an improper use of public office for private gain in violation of § 2635.702(a). However, when an arrangement is entirely voluntary and appropriate compensation is paid, a subordinate may provide services to the superior during nonduty hours. For example, a subordinate who enjoys calligraphy may prepare invitations for an upcoming party that the superior is organizing with friends and family at home on personal time for appropriate compensation. When the compensation is not adequate, however, the arrangement would involve a gift to the superior in violation of the standards in subpart C of this part.

Subpart H—Outside Activities

§ 2635.801 Overview.

(a) This subpart contains provisions relating to outside employment, outside activities, and personal financial obligations of employees that are in addition to the principles and standards set forth in other subparts of this part. Several of the provisions in this subpart apply to uncompensated as well as to compensated outside activities.

(b) Employees who wish to engage in outside employment or other outside activities must comply with all relevant provisions of this subpart, including, when applicable:

(1) The prohibition on outside employment or any other outside activity that conflicts with the employee's official duties;

(2) Any agency-specific requirement for prior approval of outside employment or activities;

(3) The limitations on receipt of outside earned income by certain Presidential appointees and other noncareer employees;

(4) The limitations on paid and unpaid service as an expert witness;

(5) The limitations on paid and unpaid teaching, speaking, and writing; and

(6) The limitations on fundraising activities.

(c) Outside employment and other outside activities of an employee must also comply with applicable provisions set forth in other subparts of this part and in supplemental agency regulations. These include the principle that an employee must endeavor to avoid actions creating an appearance of violating any of the ethical standards in this part and the prohibition against use of official position for an employee's private gain or for the private gain of any person with whom the employee has employment or business relations or is otherwise affiliated in a nongovernmental capacity.

Example 1 to paragraph (c): An employee of the Occupational Safety and Health Administration (OSHA) who was and is expected again to be instrumental in formulating new OSHA safety standards applicable to manufacturers that use chemical solvents has been offered a consulting contract to provide advice to an affected company in restructuring its manufacturing operations to comply with the OSHA standards. The

employee should not enter into the consulting arrangement even though they are not currently working on OSHA standards affecting this industry and the consulting contract can be expected to be completed before they again work on such standards. Even though the consulting arrangement would not be a conflicting activity within the meaning of § 2635.802, it would create an appearance that the employee had used their official position to obtain the compensated outside business opportunity and it would create the further appearance of using public office for the private gain of the manufacturer.

(d) In addition to the provisions of this subpart and other subparts of this part, an employee who wishes to engage in outside employment or other outside activities must comply with applicable statutes and regulations. Relevant provisions of law, many of which are listed in subpart I of this part, may include:

(1) 18 U.S.C. 201(b), which prohibits a public official from seeking, accepting or agreeing to receive or accept anything of value in return for being influenced in the performance of an official act or for being induced to take or omit to take any action in violation of official duty;

(2) 18 U.S.C. 201(c), which prohibits a public official, otherwise than as provided by law for the proper discharge of official duty, from seeking, accepting, or agreeing to receive or accept anything of value for or because of any official act;

(3) 18 U.S.C. 203(a), which prohibits an individual from seeking, accepting, or agreeing to receive or accept compensation for any representational services, rendered personally or by another at a time when the individual is an employee, in relation to any particular matter in which the United States is a party or has a direct and substantial interest, before any department, agency, or other specified entity. This statute contains several exceptions, as well as standards for special Government employees that limit the scope of the restriction;

(4) 18 U.S.C. 205, which prohibits an employee, whether or not for compensation, from acting as agent or attorney for anyone in a claim against the United States or from acting as agent or attorney for anyone, before any department, agency, or other specified entity, in any particular matter in which the United States is a party or has a direct and substantial interest. It also prohibits receipt of any gratuity, or any share of or interest in a claim against the United States, in consideration for assisting in the prosecution of such claim. This statute contains several exceptions, as well as standards for special Government employees that limit the scope of the restrictions;

(5) 18 U.S.C. 209, which prohibits an employee, other than a special Government employee, from receiving any salary or any contribution to or supplementation of salary from any source other than the United States as compensation for services as a Government employee. The statute contains several exceptions that limit its applicability;

(6) The Emoluments Clause of the United States Constitution, article I, section 9, clause 8, which prohibits anyone holding an office of profit or trust under the United States from accepting any gift, office, title, or emolument, including salary or compensation, from any foreign government except as authorized by Congress. In addition, 18 U.S.C. 219 generally prohibits any public official from being or acting as an agent of a foreign principal, including a foreign government, corporation, or person, if the employee would be required to register as a foreign agent under 22 U.S.C. 611 *et seq.;*

(7) The Hatch Act Reform Amendments, 5 U.S.C. 7321 through 7326, which govern the political activities of executive branch employees; and

(8) The Ethics in Government Act of 1978 limitations on outside employment, 5 U.S.C. chapter 131, subchapter III, which restrict the amount of outside earned income that a covered noncareer employee may receive, prohibit a covered noncareer employee from receiving compensation for specified activities, and provide that a covered noncareer employee may not allow their name to be used by any firm or other entity that provides professional services involving a fiduciary relationship. Implementing regulations are contained in §§ 2636.305 through 2636.307 of this chapter.

§ 2635.802 Conflicting outside employment and activities.

(a) Employees may not engage in outside employment or any other outside activity that conflicts with their official duties. An activity conflicts with an employee's official duties:

(1) If it is prohibited by statute or by an agency supplemental regulation; or

(2) If, under the standards set forth in §§ 2635.402 and 2635.502, it would require the employee's recusal from matters so central or critical to the performance of their official duties that the employee's ability to perform the duties of the Government position would be materially impaired.

(b) Employees are cautioned that even though an outside activity may not be prohibited under this section, it may violate other principles or standards set forth in this part or require the employee to recuse from participating in certain particular matters under either subpart D or E of this part.

Example 1 to paragraph (b): A biochemist, who conducts research at the Environmental Protection Agency (EPA), has an outside consulting business providing technical guidance on the handling of hazardous materials. The biochemist would like to apply for a different EPA position, for which the principal duty would be writing regulations on the handling of hazardous materials. If the biochemist gets the position, the work would have a direct and predictable effect on the outside consulting business. Because the biochemist would be required to recuse from duties critical to the performance of official duties on a basis so frequent as to materially impair their ability to perform the duties of the position, they could not continue to operate the outside consulting business.

Example 2 to paragraph (b): An employee of the Internal Revenue Service (IRS) reviews applications for recognition of tax-exempt status. Several years ago, the employee became involved with a neighborhood group that transports stray animals to nearby adoption centers. As its activities expanded, the group created a formal organization, and submitted an application for recognition of tax-exempt status by the IRS. Under the circumstances, the employee should be recused from participating in any IRS determination regarding the tax-exempt status of this organization. However, the employee's involvement with the organization would not be prohibited by this section, because the outside activity would have a limited effect on official duties and would not require recusal from matters so central or critical to the performance of official duties that the ability to perform the duties of the position would be materially impaired.

§ 2635.803 Prior approval for outside employment and activities.

When required by agency supplemental regulation, employees must obtain prior approval before engaging in outside employment or activities. When it is determined to be necessary or desirable for the purpose of administering its ethics program, an agency may, by supplemental regulation, require employees or any category of employees to obtain prior approval before engaging in specific types of outside activities, including

outside employment. Whether or not prior approval is required by agency supplemental regulations, employees have a continuing responsibility to ensure that their outside activities do not conflict with their official duties.

§ 2635.804 Outside earned income limitations applicable to certain Presidential appointees.

This section implements the outside earned income limitations applicable to certain Presidential appointees. The outside earned income limitations applicable to covered noncareer employees, as defined in § 2636.303(a) of this chapter, are implemented in §§ 2636.301 through 2636.304 of this chapter.

(a) *Presidential appointees to full-time noncareer positions.* A Presidential appointee to a full-time noncareer position may not receive any outside earned income for outside employment, or for any other outside activity, performed during that Presidential appointment.

(b) *Definitions.* For purposes of this section:

(1) *Outside earned income* has the meaning set forth in § 2636.303(b) of this chapter, except that § 2636.303(b)(7) does not apply.

(2) *Presidential appointee to a full-time noncareer position* means any employee who is appointed by the President to a full-time position described in 5 U.S.C. 5312 through 5317 or to a position that, by statute or as a matter of practice, is filled by Presidential appointment, other than:

(i) A position filled under the authority of 3 U.S.C. 105 or 107(a) for which the rate of basic pay is less than that for GS–9, step 1 of the General Schedule;

(ii) A position, within a White House operating unit, that is designated as not normally subject to change as a result of a Presidential transition;

(iii) A position within the uniformed services; or

(iv) A position in which a member of the Foreign Service is serving that does not require advice and consent of the Senate.

Example 1 to paragraph (b)(2): A career Department of Justice employee who is detailed to a policy-making position in the White House Office that is ordinarily filled by a noncareer employee is not a Presidential appointee to a full-time noncareer position.

Example 2 to paragraph (b)(2): A Department of Energy employee appointed under § 213.3301 of this title to a Schedule C position is appointed by the agency and, thus, is not a Presidential appointee to a full-time noncareer position.

§ 2635.805 Service as an expert witness.

(a) *Restriction.* Employees may not serve, other than on behalf of the United States, as an expert witness, with or without compensation, in any proceeding before a court or agency of the United States in which the United States is a party or has a direct and substantial interest, unless the employee's participation is authorized by the agency under paragraph (c) of this section. Except as provided in paragraph (b) of this section, the restriction in this paragraph (a) applies to special Government employees only if they have participated as an employee or special Government employee in the particular proceeding or in the particular matter that is the subject of the proceeding.

(b) *Additional restriction applicable to certain special Government employees.* (1) In addition to the restriction described in paragraph (a) of this section, special Government employees described in paragraph (b)(2) of this section may not serve, other than on behalf of the United States, as an expert witness, with or without compensation, in any proceeding before a court or agency of the United States in which their employing agency is a party or has a direct and substantial interest, unless the employee's participation is authorized by the agency under paragraph (c) of this section.

(2) The restriction in paragraph (b)(1) of this section applies to special Government employees who:

(i) Are appointed by the President;

(ii) Serve on a commission established by statute; or

(iii) Have served or are expected to serve for more than 60 days in a period of 365 consecutive days.

(c) *Authorization to serve as an expert witness.* Provided that the employee's testimony will not violate any of the principles or standards set forth in this part, authorization to provide expert witness service otherwise prohibited by paragraphs (a) and (b) of this section may be given by the designated agency ethics official of the agency in which the employee serves when:

(1) After consultation with the agency representing the Government in the proceeding or, if the Government is not a party, with the Department of Justice and the agency with the most direct and substantial interest in the matter, the designated agency ethics official determines that the employee's service as an expert witness is in the interest of the Government; or

(2) The designated agency ethics official determines that the subject matter of the testimony does not relate to the employee's official duties within the meaning of § 2635.807(a)(2)(i).

(d) *Fact witness.* Nothing in this section prohibits an employee from serving as a fact witness when subpoenaed by an appropriate authority.

§ 2635.806 [Reserved]

§ 2635.807 Teaching, speaking, and writing.

(a) *Compensation for teaching, speaking, or writing.* Except for teaching certain courses as permitted by paragraph (a)(3) of this section, an employee, including a special Government employee, may not receive compensation from any source other than the Government for teaching, speaking, or writing that occurs while the person is a Government employee and that relates to the employee's official duties.

(1) *Relationship to other limitations on receipt of compensation.* The compensation prohibition contained in this section is in addition to any other limitation on receipt of compensation set forth in this chapter, including:

(i) The requirement contained in § 2636.307 of this chapter that covered noncareer employees obtain advance authorization before engaging in teaching for compensation; and

(ii) The prohibitions and limitations in § 2635.804 and in § 2636.304 of this chapter on receipt of outside earned income applicable to certain Presidential appointees and to other covered noncareer employees.

(2) *Definitions.* For purposes of this paragraph (a):

(i) Teaching, speaking, or writing *relates to the employee's official duties* if:

(A) The activity is undertaken as part of the employee's official duties;

(B) The circumstances indicate that the invitation to engage in the activity was extended to the employee primarily because of their official position rather than their expertise on the particular subject matter;

(C) The invitation to engage in the activity or the offer of compensation for the activity was extended to the employee, directly or indirectly, by a person who has interests that may be affected substantially by performance or nonperformance of the employee's official duties;

(D) The information conveyed through the activity draws substantially on ideas or official data that are nonpublic information as defined in § 2635.703(b); or

(E) Except as provided in paragraph (a)(2)(i)(E)(*4*) of this section, the subject of the activity deals in significant part with:

(*1*) Any matter to which the employee presently is assigned or to which the employee had been assigned during the previous one-year period;

(*2*) Any ongoing or announced policy, program, or operation of the agency; or

(*3*) In the case of a noncareer employee as defined in § 2636.303(a) of this chapter, the general subject matter area, industry, or economic sector primarily affected by the programs and operations of the employee's agency.

(*4*) The restrictions in paragraphs (a)(2)(i)(E)(*2*) and (*3*) of this section do not apply to a special Government employee. The restriction in paragraph (a)(2)(i)(E)(*1*) of this section applies only during the current appointment of a special Government employee; except that if the special Government employee has not served or is not expected to serve for more than 60 days during the first year or any subsequent one-year period of that appointment, the restriction applies only to particular matters involving specific parties in which the special Government employee has participated or is participating personally and substantially.

Note 1 to paragraph (a)(2)(i): Paragraph (a)(2)(i)(E) of this section does not preclude an employee, other than a covered noncareer employee, from receiving compensation for teaching, speaking, or writing on a subject within the employee's discipline or inherent area of expertise based on the employee's educational background or experience even though the teaching, speaking, or writing deals generally with a subject within the agency's areas of responsibility.

Example 1 to paragraph (a)(2)(i): The Director of the Division of Enforcement at the Commodity Futures Trading Commission has a keen interest in stamp collecting and has spent years developing a personal collection as well as studying the field generally. The Director is asked by an international society of philatelists to give a series of four lectures on how to assess the value of American stamps. Because the subject does not relate to the Director's official duties, it is permissible for the Director to accept compensation for the lecture series. The Director could not, however, accept a similar invitation from a commodities broker.

Example 2 to paragraph (a)(2)(i): A scientist at the National Institutes of Health (NIH), whose principal area of Government research is the molecular basis of the development of cancer, could not be compensated for writing a book which focuses specifically on the research conducted in this position at NIH, which thus relates to the scientist's official duties. However, the scientist could receive compensation for writing or editing a textbook on the treatment of all cancers, provided that the book does not focus on recent research at NIH, but rather conveys scientific knowledge gleaned from the scientific community as a whole. The book might include a chapter, among many other chapters, which discusses the molecular basis of cancer development. Additionally, the book could contain brief discussions of recent developments in cancer treatment, even though some of those developments are derived from NIH research, as long as it is available to the public.

Example 3 to paragraph (a)(2)(i): On personal time, a National Highway Traffic Safety Administration (NHTSA) employee prepared a consumer's guide to purchasing a safe automobile that focuses on automobile crash worthiness statistics gathered and made public by NHTSA. The employee may not receive royalties or any other form of compensation for the guide. The guide deals in significant part with the programs or operations of NHTSA and, therefore, relates to the employee's official duties. On the other hand, the employee could receive royalties from the sale of a consumer's guide to values in used automobiles even though it contains a brief, incidental discussion of automobile safety standards developed by NHTSA.

Example 4 to paragraph (a)(2)(i): An employee of the Securities and Exchange Commission (SEC) may not receive compensation for a book which focuses specifically on the regulation of the securities industry in the United States, because that subject concerns the regulatory programs or operations of the SEC. The employee may, however, write a book about the advantages of investing in various types of securities as long as the book contains only an incidental discussion of any program or operation of the SEC.

Example 5 to paragraph (a)(2)(i): An employee of the Department of Commerce who works in the Department's employee relations office is an acknowledged expert in the field of Federal employee labor relations, and participates in Department negotiations with employee unions. The employee may receive compensation from a private training institute for a series of lectures which describe the decisions of the Federal Labor Relations Authority concerning unfair labor practices, provided that the lectures do not contain any significant discussion of labor relations cases handled at the Department of Commerce, or the Department's labor relations policies. Federal Labor Relations Authority decisions concerning Federal employee unfair labor practices are not a specific program or operation of the Department of Commerce and thus do not relate to the employee's official duties. However, an employee of the FLRA could not give the same presentations for compensation.

Example 6 to paragraph (a)(2)(i): A program analyst employed at the Environmental Protection Agency (EPA) may receive royalties and other compensation for a book about the history of the environmental movement in the United States even though it contains brief references to the creation and responsibilities of the EPA. A covered noncareer employee of the EPA, however, could not receive compensation for writing the same book because it deals with the general subject matter area affected by EPA programs and operations. Neither employee could receive compensation for writing a book that focuses on specific EPA regulations or otherwise on its programs and operations.

Example 7 to paragraph (a)(2)(i): An attorney in private practice has been given a one-year appointment as a special Government employee to serve on an advisory committee convened for the purpose of surveying and recommending modification of procurement regulations that deter small businesses from competing for Government contracts. Because service under this appointment is not expected to exceed 60 days, the attorney may accept compensation for an article about the anticompetitive effects of certain regulatory certification requirements even though those regulations are being reviewed by the advisory committee. The regulations which are the focus of the advisory committee deliberations are not a particular matter involving specific parties. Because the information is nonpublic, the attorney could not, however, accept compensation for an article which recounts advisory committee deliberations that took place in a meeting closed to the public in order to discuss proprietary information provided by a small business.

Example 8 to paragraph (a)(2)(i): A biologist who is an expert in marine life is employed for more than 60 days in a year as a special Government employee by the National Science Foundation (NSF) to assist in developing a program of grants by the NSF for the study of coral reefs. The biologist may continue to receive compensation for speaking, teaching, and writing about marine life generally and coral reefs specifically. However, during the term of the appointment as a special Government employee, the biologist may not receive compensation for an article about the

NSF program being developed. Only the latter would concern a matter to which the special Government employee is assigned.

Example 9 to paragraph (a)(2)(i): An expert on international banking transactions has been given a one-year appointment as a special Government employee to assist in analyzing evidence in the Government's fraud prosecution of owners of a failed savings and loan association. It is anticipated that the expert will serve fewer than 60 days under that appointment. Nevertheless, during this appointment, the expert may not accept compensation for an article about the fraud prosecution, even though the article does not reveal nonpublic information. The prosecution is a particular matter that involves specific parties.

(ii) *Agency* has the meaning set forth in § 2635.102(a), except that any component of a department designated as a separate agency under § 2635.203(a) will be considered a separate agency.

(iii) *Compensation,* for purposes of this paragraph (a):

(A) Includes any form of consideration, remuneration, or income, including royalties, given for or in connection with the employee's teaching, speaking, or writing.

(B) *Compensation* does not include:

(*1*) Items offered by any source that could be accepted from a prohibited source under subpart B of this part;

(*2*) Meals or other incidents of attendance such as waiver of attendance fees or course materials furnished as part of the event at which the teaching or speaking takes place;

(*3*) Copies of books or of publications containing articles, reprints of articles, tapes of speeches, and similar items that provide a record of the teaching, speaking, or writing activity; or

(*4*) Travel expenses for certain individuals as described in paragraph (a)(2)(iii)(C) of this section.

(C) For employees other than covered noncareer employees as defined in § 2636.303(a) of this chapter, *compensation* does not include travel expenses, consisting of transportation, lodging or meals, incurred in connection with the teaching, speaking, or writing activity. For covered noncareer employees as defined in § 2636.303(a) of this chapter, *compensation* does include transportation, lodging, and meals, whether provided in kind, by purchase of a ticket, by payment in advance, or by reimbursement after the expense has been incurred, unless such travel expenses are accepted under specific statutory authority, such as 31 U.S.C. 1353, 5 U.S.C. 4111, or 5 U.S.C. 7342, or an agency gift acceptance statute.

Note 2 to paragraph (a)(2)(iii)(C): Independent of paragraph (a) of this section, other authorities, including but not limited to 18 U.S.C. 209, in some circumstances may limit or entirely preclude an employee's acceptance of travel expenses. In addition, employees who file financial disclosure reports should be aware that, subject to applicable thresholds and exclusions, travel and travel reimbursements accepted from sources other than the United States Government must be reported on their financial disclosure reports.

Example 1 to paragraph (a)(2)(iii): A GS–15 employee of the Forest Service has developed and marketed, in a private capacity, a speed-reading technique for which popular demand is growing. The employee is invited to speak about the technique by a representative of an organization that will be substantially affected by a regulation on land management which the employee is in the process of drafting for the Forest Service. The representative offers to pay the employee a $200 speaker's fee and to reimburse all travel expenses. The employee may accept the travel reimbursements, but not the speaker's fee. The speaking activity is related to official duties under paragraph (a)(2)(i)(C) of this section and the fee is prohibited compensation for such speech; travel expenses incurred in connection with the speaking engagement, on the other hand, are not prohibited compensation for a GS–15 employee.

Example 2 to paragraph (a)(2)(iii): Solely because of their recent appointment to a Cabinet-level position, a Government official is invited by the Chief Executive Officer of a major international corporation to attend, in their personal capacity, firm meetings to be held in Aspen for the purpose of addressing senior corporate managers on the importance of recreational activities to a balanced lifestyle. The firm offers to reimburse the official's travel expenses. The official may not accept the offer. The speaking activity is related to official duties under paragraph (a)(2)(i)(B) of this section and, because the official is a covered noncareer employee as defined in § 2636.303(a) of this chapter, the travel expenses are prohibited compensation.

Example 3 to paragraph (a)(2)(iii): A GS–14 attorney at the Federal Trade Commission (FTC) who played a lead role in a recently concluded merger case is invited to speak about the case, in a private capacity, at a conference in New York. The attorney has no public speaking responsibilities on behalf of the FTC apart from the judicial and administrative proceedings to which they are assigned. The sponsors of the conference offer to reimburse the attorney for expenses incurred in connection with the travel to New York. They also offer the attorney, as compensation for time and effort, a free trip to San Francisco. The attorney may accept the travel expenses to New York, but not the expenses to San Francisco. The lecture relates to official duties under paragraphs (a)(2)(i)(E)(*1*) and (*2*) of this section, but because the attorney is not a covered noncareer employee as defined in § 2636.303(a) of this chapter, the expenses associated with the travel to New York are not a prohibited form of compensation. The travel expenses to San Francisco, on the other hand, not incurred in connection with the speaking activity, are a prohibited form of compensation. If the attorney were a covered noncareer employee, the travel expenses to New York as well as the travel expenses to San Francisco would be barred.

Example 4 to paragraph (a)(2)(iii): An advocacy group dedicated to improving treatments for severe pain asks the National Institutes of Health (NIH) to provide a conference speaker who can discuss recent advances in the agency's research on pain. The group also offers to pay the employee's travel expenses to attend the conference. After performing the required conflict of interest analysis, NIH authorizes acceptance of the travel expenses under 31 U.S.C. 1353 and the implementing General Services Administration regulation, as codified under 41 CFR chapter 304, and authorizes an employee to undertake the travel. At the conference the advocacy group, as agreed, pays the employee's hotel bill, and provides several of the employee's meals. Subsequently the group reimburses the agency for the cost of the employee's airfare and some additional meals. All of the payments by the advocacy group are permissible. Because the employee is speaking officially and the expense payments are accepted under 31 U.S.C. 1353, they are not prohibited compensation under paragraph (a)(2)(iii) of this section. The same result would obtain with respect to expense payments made by non-Government sources properly authorized under an agency gift acceptance statute, the Government Employees Training Act, 5 U.S.C. 4111, or the Foreign Gifts and Decorations Act, 5 U.S.C. 7342.

(iv) *Receive* means that there is actual or constructive receipt of the compensation by the employee so that the employee has the right to exercise dominion and control over the

compensation and to direct its subsequent use. Receipt of compensation is attributable to the time that the teaching, speaking, or writing occurs when there is actual or constructive receipt of the compensation by the employee. If the employee has an enforceable agreement to receive compensation for writing undertaken during Government service, then compensation is received while the individual is an employee even though actual payment may be deferred until after Government service. Compensation received by an employee includes compensation which is:

(A) Paid to another person, including a charitable organization, on the basis of designation, recommendation, or other specification by the employee; or

(B) Paid with the employee's knowledge and acquiescence to the employee's parent, sibling, spouse, child, or dependent relative.

(v) *Particular matter involving specific parties* has the meaning set forth in § 2640.102(l) of this chapter.

(vi) *Personal and substantial participation* has the meaning set forth in § 2635.402(b)(4).

(3) *Exception for teaching certain courses.* Notwithstanding that the activity would relate to their official duties under paragraph (a)(2)(i)(B) or (E) of this section, employees may accept compensation for teaching a course requiring multiple presentations by the employee if the course is offered as part of:

(i) The regularly established curriculum of:

(A) An institution of higher education as defined at 20 U.S.C. 1001 or from a similar foreign institution of higher education;

Note 3 to paragraph (a)(3)(i)(A): When the course is offered as part of the regularly established curriculum of a foreign institution of higher education, the agency may need to make a separate determination as to whether the institution of higher education is a foreign government for purposes of the Emoluments Clause of the U.S. Constitution (U.S. Const., art. I, sec. 9, cl. 8), which forbids employees from accepting emoluments, presents, offices, or titles from foreign governments, without the consent of Congress.

(B) An elementary school as defined at 20 U.S.C. 7801(19); or

(C) A secondary school as defined at 20 U.S.C. 7801(45); or

(ii) A program of education or training sponsored and funded by the Federal Government or by a State or local government which is not offered by an entity described in paragraph (a)(3)(i) of this section.

Example 1 to paragraph (a)(3): An employee of the Cost Accounting Standards Board who teaches an advanced accounting course as part of the regular business school curriculum of an accredited university may receive compensation for teaching the course even though a substantial portion of the course deals with cost accounting principles applicable to contracts with the Government.

Example 2 to paragraph (a)(3): An attorney employed by the Equal Employment Opportunity Commission (EEOC) may accept compensation for teaching a course at a state college on the subject of EEOC enforcement of Federal employment discrimination law. The attorney could not accept compensation for teaching the same seminar as part of a continuing education program sponsored by a bar association because the subject of the course is focused on the operations or programs of the EEOC, and the sponsor of the course is not an accredited educational institution.

Example 3 to paragraph (a)(3): An employee of the National Endowment for the Humanities (NEH) is invited by a private university to teach a course that is a survey of Government policies in support of artists, poets, and writers. As part of official duty activities, the employee administers a grant that the university has received from the NEH. The employee may not accept compensation for teaching the course because the university has interests that may be substantially affected by the performance or nonperformance of the employee's duties. Likewise, an employee may not receive compensation for any teaching that is undertaken as part of official duties or that involves the use of nonpublic information.

(b) *Reference to official position.* Employees who are engaged in teaching, speaking, or writing as outside employment or as an outside activity may not use or permit the use of their official title or position to identify themselves in connection with a teaching, speaking, or writing activity, or to promote any book, seminar, course, program, or similar undertaking, except that:

(1) Employees may include or permit the inclusion of their title or position as one of several biographical details when such information is given to identify them in connection with their teaching, speaking, or writing, provided that their title or position is given no more prominence than other significant biographical details;

(2) Employees may use or permit the use of their title or position in connection with an article published in a scientific or professional journal, provided that the title or position is accompanied by a reasonably prominent disclaimer satisfactory to the agency stating that the views expressed in the article do not necessarily represent the views of the agency or the United States; and

(3) Employees who are ordinarily addressed using a general term of address, such as ''The Honorable'' or ''Judge,'' or a rank, such as a military or ambassadorial rank, may use or permit the use of that term of address or rank in connection with their teaching, speaking, or writing.

Note 4 to paragraph (b): Reference to official title and position other than in a teaching, speaking, or writing capacity may be made only as permitted by § 2635.702(b). In addition, some agencies may have policies requiring advance agency review, clearance, or approval of certain speeches, books, articles, or similar products to determine whether the product contains an appropriate disclaimer, discloses nonpublic information, or otherwise complies with this section.

Example 1 to paragraph (b): A meteorologist employed with the National Oceanic and Atmospheric Administration (NOAA) is asked by a local university to teach a graduate course on hurricanes. The university may include the meteorologist's Government title and position together with other information about the meteorologist's education and previous employment in course materials setting forth biographical data on all teachers involved in the graduate program. However, the meteorologist's title or position may not be used to promote the course, for example, by featuring the meteorologist's Government title, Senior Meteorologist, NOAA, in bold type under their name. In contrast, the meteorologist's title may be used in this manner when NOAA authorized speaking in an official capacity.

Example 2 to paragraph (b): A doctor just employed by the Centers for Disease Control (CDC) has written a paper based on earlier independent research into cell structures. Incident to the paper's publication in the Journal of the American Medical Association, the doctor may be given credit for the paper, as Dr. M. Wellbeing, Associate Director, Centers for Disease Control, provided that the article also contains a disclaimer, concurred in by the CDC, indicating that the paper is the result of the doctor's independent research and does not represent the findings of the CDC.

Example 3 to paragraph (b): An employee of the Federal Deposit Insurance Corporation (FDIC) has been asked to give a speech in a private capacity, without compensation, to the

annual meeting of a committee of the American Bankers Association on the need for banking reform. The employee may be described in an introduction at the meeting as an employee of the FDIC provided that other pertinent biographical details are mentioned as well.

§ 2635.808 Fundraising activities.

Employees may engage in fundraising only in accordance with the restrictions in part 950 of this title on the conduct of charitable fundraising in the Federal workplace and in accordance with paragraphs (b) and (c) of this section. This section addresses fundraising as defined in paragraph (a)(1) of this section, and does not cover all scenarios in which an employee might seek to collect donations from a fellow employee. For example, employees of an office might decide to collect money for a coworker whose family was displaced by a flood; the permissibility of such collections should be analyzed under subpart C of this part, not this section.

(a) *Definitions.* For purposes of this section:

(1) *Fundraising* means the raising of funds for a nonprofit organization, other than a political organization as defined in 26 U.S.C. 527(e), through:

(i) Solicitation of funds or sale of items; or

(ii) Participation in the conduct of an event by an employee when any portion of the cost of attendance or participation may be taken as a charitable tax deduction by a person incurring that cost.

(2) *Participation in the conduct of an event* means active and visible participation in the promotion, production, or presentation of the event and includes serving as honorary chairperson, sitting at a head table during the event, and standing in a reception line. The term does not include mere attendance at an event provided that, to the employee's knowledge, the employee's attendance is not used by the nonprofit organization to promote the event. While the term generally includes any public speaking during the event, it does not include the delivery of an official speech as defined in paragraph (a)(3) of this section or any seating or other participation appropriate to the delivery of such a speech. Waiver of a fee for attendance at an event by a participant in the conduct of that event does not constitute a gift for purposes of subpart B of this part.

Example 1 to paragraph (a)(2): The Secretary of Transportation has been asked to serve as master of ceremonies for an All-Star Gala. Tickets to the event cost $150 and are tax deductible as a charitable donation, with proceeds to be donated to a local hospital. By serving as master of ceremonies, the Secretary would be participating in fundraising.

(3) *Official speech* means a speech given by an employee in an official capacity on a subject matter that relates to the employee's official duties, provided that the employee's agency has determined that the event at which the speech is to be given provides an appropriate forum for the dissemination of the information to be presented and provided that the employee does not request donations or other support for the nonprofit organization. Subject matter relates to an employee's official duties if it focuses specifically on the employee's official duties, on the responsibilities, programs, or operations of the employee's agency as described in § 2635.807(a)(2)(i)(E), or on matters of Administration policy on which the employee has been authorized to speak.

Example 1 to paragraph (a)(3): The Secretary of Labor is invited to speak at a banquet honoring a distinguished labor leader, the proceeds of which will benefit a nonprofit organization that assists homeless families. The Secretary devotes a major portion of the speech to the Administration's Points of Light initiative, an effort to encourage citizens to volunteer their time to help solve serious social problems. Because the Secretary is authorized to speak on Administration policy, these remarks at the banquet are an official speech. However, the Secretary would be engaged in fundraising if the official speech concluded with a request for donations to the nonprofit organization.

Example 2 to paragraph (a)(3): A charitable organization is sponsoring a two-day tennis tournament at a country club in the Washington, DC, area to raise funds for recreational programs for children with learning disabilities. The organization has invited the Secretary of Education to give a speech on federally funded special education programs at the awards dinner to be held at the conclusion of the tournament, and the agency has determined that the dinner is an appropriate forum for the particular speech. The Secretary may speak at the dinner and, under § 2635.203(b)(8), may partake of the meal provided at the dinner.

(4) *Personally solicit* means to request or otherwise encourage donations or other support either through person-to-person contact or through the use of one's name or identity in correspondence or by permitting its use by others. It does not include the solicitation of funds through the media or through either oral remarks, or the contemporaneous dispatch of like items of mass-produced correspondence, if such remarks or correspondence are addressed to a group consisting of many persons, unless it is known to the employee that the solicitation is targeted at subordinates or at persons who are prohibited sources within the meaning of § 2635.203(d). It does not include behind-the-scenes assistance in the solicitation of funds, such as drafting correspondence, stuffing envelopes, or accounting for contributions.

Example 1 to paragraph (a)(4): An employee of the Department of Energy (DOE) who signs a letter soliciting funds for a local private school does not ''personally solicit'' funds when 500 copies of the letter, which makes no mention of the employee's DOE position and title, are mailed to members of the local community, even though some individuals who are employed by DOE contractors may receive the letter.

(b) *Fundraising in an official capacity.* Employees may participate in fundraising in an official capacity if, in accordance with a statute, Executive order, regulation, or otherwise as determined by the agency, they are authorized to engage in the fundraising activity as part of their official duties. When authorized to participate in an official capacity, employees may use their official title, position, and authority.

Example 1 to paragraph (b): Because participation in an official capacity is authorized under part 950 of this title, the Secretary of the Army may sign a memorandum to all Army personnel encouraging them to donate to the Combined Federal Campaign.

(c) *Fundraising in a personal capacity.* An employee may engage in fundraising in a personal capacity provided that the employee does not:

(1) Personally solicit funds or other support from a subordinate or from any person:

(i) Known to the employee, if the employee is other than a special Government employee, to be a prohibited source within the meaning of § 2635.203(d), unless the circumstances make clear that the solicitation is motivated by a family relationship or personal friendship that would justify the solicitation; or

(ii) Known to the employee, if the employee is a special Government employee, to be a prohibited source within the meaning of § 2635.203(d)(4) that is a person whose interests may be substantially affected by performance or nonperformance of the employee's official duties, unless the circumstances make clear that the solicitation is

motivated by a family relationship or personal friendship that would justify the solicitation;

(2) Use or permit the use of the employee's official title, position, or any authority associated with the employee's public office to further the fundraising effort, except that an employee who is ordinarily addressed using a general term of address, such ''The Honorable,'' or a rank, such as a military or ambassadorial rank, may use or permit the use of that term of address or rank for such purposes; or

(3) Engage in any action that would otherwise violate this part.

Note 1 to paragraph (c): This section does not prohibit fundraising for a political party, candidate for partisan political office, or partisan political group. However, there are statutory restrictions that apply to political fundraising. For example, under the Hatch Act Reform Amendments of 1993, at 5 U.S.C. 7323(a), employees may not knowingly solicit, accept, or receive a political contribution from any person, except under limited circumstances. In addition, employees are prohibited by 18 U.S.C. 607 from soliciting or receiving political contributions in Federal offices, and, except as permitted by the Hatch Act Reform Amendments, are prohibited by 18 U.S.C. 602 from knowingly soliciting political contributions from other employees.

Example 1 to paragraph (c): A nonprofit organization is sponsoring a golf tournament to raise funds for underprivileged children. The Secretary of the Navy may not enter the tournament with the understanding that the organization intends to attract participants by offering other entrants the opportunity, in exchange for a donation in the form of an entry fee, to spend the day playing 18 holes of golf in a foursome with the Secretary of the Navy.

Example 2 to paragraph (c): An employee of the Merit Systems Protection Board may not use the agency's photocopier to reproduce fundraising literature for their child's private school. Such use of the photocopier would violate the standards at § 2635.704 regarding use of Government property.

Example 3 to paragraph (c): An Assistant Attorney General may not sign a letter soliciting funds for a homeless shelter as ''P.J. Doe, Assistant Attorney General.'' The Assistant Attorney General also may not sign a letter with just a ''P.J. Doe'' signature soliciting funds from a prohibited source, unless the letter is one of many identical, mass-produced letters addressed to a large group when the solicitation is not known to the Assistant Attorney General to be targeted at persons who are either prohibited sources or subordinates.

Example 4 to paragraph (c): An employee of the Department of Commerce is running a half marathon to raise money for a nonprofit organization engaged in cancer research, and is looking for people to sponsor the race. The employee plans to target specific individuals they think will want to contribute, including a close friend with whom they regularly meet for dinner. Notwithstanding the fact that the friend is employed by a corporation that is a prohibited source, the employee may ask the friend to sponsor the race because the solicitation is motivated by a personal friendship that would justify the solicitation.

Example 5 to paragraph (c): The employee in example 4 to this paragraph (c) knows that a subordinate employee has expressed an interest in this cause and sends the subordinate a direct link to the online sponsorship page. The employee has ''personally solicited'' a subordinate in violation of paragraph (c)(1) of this section.

Example 6 to paragraph (c): The employee in example 4 to this paragraph (c) decides that rather than targeting specific individuals for contributions, it would be preferable to post a general request and a link to information about the race on their personal social media account. Because this request may be viewed by any person with whom the employee is connected through the social media network and does not reference or target any specific individual, it is not considered a personal solicitation of any subordinate or prohibited source that is connected to the employee.

§ 2635.809 Just financial obligations.

Employees must satisfy in good faith their obligations as citizens, including all just financial obligations, especially those such as Federal, State, or local taxes that are imposed by law. For purposes of this section, a just financial obligation includes any financial obligation acknowledged by the employee or reduced to judgment by a court. In good faith means an honest intention to fulfill any just financial obligation in a timely manner. In the event of a dispute between an employee and an alleged creditor, this section does not require an agency to determine the validity or amount of the disputed debt or to collect a debt on the alleged creditor's behalf.

Subpart I—Related Statutory Authorities

§ 2635.901 General.

In addition to the Standards of Ethical Conduct set forth in subparts A through H of this part, there are a number of statutes that establish standards to which an employee's conduct must conform. The list set forth in § 2635.902 references some of the more significant of those statutes. It is not comprehensive and includes only references to statutes of general applicability. While it includes references to several of the basic conflict of interest statutes whose standards are explained in more detail throughout this part, it does not include references to statutes of more limited applicability, such as statutes that apply only to officers and employees of the Department of Defense.

§ 2635.902 Related statutes.

(a) The prohibition against solicitation or receipt of bribes (18 U.S.C. 201(b)).

(b) The prohibition against solicitation or receipt of illegal gratuities (18 U.S.C. 201(c)).

(c) The prohibition against seeking or receiving compensation for certain representational services before the Government (18 U.S.C. 203).

(d) The prohibition against assisting in the prosecution of claims against the Government or acting as agent or attorney before the Government (18 U.S.C. 205).

(e) The post-employment restrictions applicable to former employees (18 U.S.C. 207 and the regulation at part 2641 of this chapter).

(f) The prohibition on certain former agency officials' acceptance of compensation from a contractor (41 U.S.C. 2104).

(g) The prohibition against participating in matters affecting an employee's own financial interests or the financial interests of other specified persons or organizations (18 U.S.C. 208 and the regulation at part 2640 of this chapter).

(h) The actions required of certain agency officials when they contact, or are contacted by, offerors or bidders regarding non-Federal employment (41 U.S.C. 2103).

(i) The prohibition against receiving salary or any contribution to or supplementation of salary as compensation for Government service from a source other than the United States (18 U.S.C. 209).

(j) The prohibition against gifts to superiors (5 U.S.C. 7351).

(k) The prohibition against solicitation or receipt of gifts from

specified prohibited sources (5 U.S.C. 7353).

(l) The prohibition against fraudulent access and related activity in connection with computers (18 U.S.C. 1030).

(m) The provisions governing receipt and disposition of foreign gifts and decorations (5 U.S.C. 7342).

(n) [Reserved]

(o) The prohibitions against certain political activities (5 U.S.C. 7321 through 7326 and 18 U.S.C. 602, 603, 606, and 607).

(p) The prohibitions against disloyalty and striking (5 U.S.C. 7311 and 18 U.S.C. 1918).

(q) The general prohibition (18 U.S.C. 219) against acting as the agent of a foreign principal required to register under the Foreign Agents Registration Act (22 U.S.C. 611 through 621).

(r) The prohibition against employment of a person convicted of participating in or promoting a riot or civil disorder (5 U.S.C. 7313).

(s) The prohibition against employment of an individual who habitually uses intoxicating beverages to excess (5 U.S.C. 7352).

(t) The prohibition against misuse of a Government vehicle (31 U.S.C. 1344).

(u) The prohibition against misuse of the franking privilege (18 U.S.C. 1719).

(v) The prohibition against fraud or false statements in a Government matter (18 U.S.C. 1001).

(w) The prohibition against concealing, mutilating, or destroying a public record (18 U.S.C. 2071).

(x) The prohibition against counterfeiting or forging transportation requests (18 U.S.C. 508).

(y) The restrictions on disclosure of certain sensitive Government information under the Freedom of Information Act and the Privacy Act (5 U.S.C. 552 and 552a).

(z) The prohibitions against disclosure of classified information (18 U.S.C. 798 and 50 U.S.C. 783(a)).

(aa) The prohibition against disclosure of proprietary information and certain other information of a confidential nature (18 U.S.C. 1905).

(bb) The prohibitions on disclosing and obtaining certain procurement information (41 U.S.C. 2102).

(cc) The prohibition against unauthorized use of documents relating to claims from or by the Government (18 U.S.C. 285).

(dd) The prohibition against certain personnel practices (5 U.S.C. 2302).

(ee) The prohibition against interference with civil service examinations (18 U.S.C. 1917).

(ff) The restrictions on use of public funds for lobbying (18 U.S.C. 1913).

(gg) The prohibition against participation in the appointment or promotion of relatives (5 U.S.C. 3110).

(hh) The prohibition against solicitation or acceptance of anything of value to obtain public office for another (18 U.S.C. 211).

(ii) The prohibition against conspiracy to commit an offense against or to defraud the United States (18 U.S.C. 371).

(jj) The prohibition against embezzlement or conversion of Government money or property (18 U.S.C. 641).

(kk) The prohibition against failing to account for public money (18 U.S.C. 643).

(ll) The prohibition against embezzlement of the money or property of another person that is in the possession of an employee by reason of their employment (18 U.S.C. 654).

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